

107TH CONGRESS
1ST SESSION

S. 6

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

IN THE SENATE OF THE UNITED STATES

JANUARY 22, 2001

Mr. DASCHLE (for himself, Mr. KENNEDY, Mr. AKAKA, Mr. BIDEN, Mr. BINGAMAN, Mrs. BOXER, Mr. BYRD, Mrs. CARNAHAN, Mr. CARPER, Mr. CLELAND, Mrs. CLINTON, Mr. CONRAD, Mr. CORZINE, Mr. DAYTON, Mr. DODD, Mr. DORGAN, Mr. DURBIN, Mr. EDWARDS, Mr. GRAHAM, Mr. HARKIN, Mr. HOLLINGS, Mr. INOUE, Mr. JOHNSON, Mr. KERRY, Ms. LANDRIEU, Mr. LEAHY, Mr. LEVIN, Ms. MIKULSKI, Mrs. MURRAY, Mr. NELSON of Florida, Mr. REED, Mr. REID, Mr. ROCKEFELLER, Mr. SARBANES, Mr. SCHUMER, Ms. STABENOW, Mr. TORRICELLI, Mr. WELLSTONE, and Mr. WYDEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Patients’ Bill of Rights Act”.

4 (b) TABLE OF CONTENTS.—The table of contents of
5 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—IMPROVING MANAGED CARE

Subtitle A—Grievance and Appeals

Sec. 101. Utilization review activities.
Sec. 102. Internal appeals procedures.
Sec. 103. External appeals procedures.
Sec. 104. Establishment of a grievance process.

Subtitle B—Access to Care

Sec. 111. Consumer choice option.
Sec. 112. Choice of health care professional.
Sec. 113. Access to emergency care.
Sec. 114. Access to specialty care.
Sec. 115. Access to obstetrical and gynecological care.
Sec. 116. Access to pediatric care.
Sec. 117. Continuity of care.
Sec. 118. Access to needed prescription drugs.
Sec. 119. Coverage for individuals participating in approved clinical trials.

Subtitle C—Access to Information

Sec. 121. Patient access to information.

Subtitle D—Protecting the Doctor-Patient Relationship

Sec. 131. Prohibition of interference with certain medical communications.
Sec. 132. Prohibition of discrimination against providers based on licensure.
Sec. 133. Prohibition against improper incentive arrangements.
Sec. 134. Payment of claims.
Sec. 135. Protection for patient advocacy.

Subtitle E—Definitions

Sec. 151. Definitions.
Sec. 152. Preemption; State flexibility; construction.
Sec. 153. Exclusions.
Sec. 154. Coverage of limited scope plans.
Sec. 155. Regulations.

**TITLE II—APPLICATION OF QUALITY CARE STANDARDS TO
GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE
UNDER THE PUBLIC HEALTH SERVICE ACT**

Sec. 201. Application to group health plans and group health insurance coverage.

Sec. 202. Application to individual health insurance coverage.

TITLE III—AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

Sec. 301. Application of patient protection standards to group health plans and group health insurance coverage under the Employee Retirement Income Security Act of 1974.

Sec. 302. ERISA preemption not to apply to certain actions involving health insurance policyholders.

Sec. 303. Limitations on actions.

TITLE IV—APPLICATION TO GROUP HEALTH PLANS UNDER THE INTERNAL REVENUE CODE OF 1986

Sec. 401. Amendments to the Internal Revenue Code of 1986.

TITLE V—EFFECTIVE DATES; COORDINATION IN IMPLEMENTATION

Sec. 501. Effective dates.

Sec. 502. Coordination in implementation.

TITLE VI—MISCELLANEOUS PROVISIONS

Sec. 601. Health care paperwork simplification.

Sec. 602. No impact on social security trust fund.

1 **TITLE I—IMPROVING MANAGED** 2 **CARE**

3 **Subtitle A—Grievance and Appeals**

4 **SEC. 101. UTILIZATION REVIEW ACTIVITIES.**

5 (a) COMPLIANCE WITH REQUIREMENTS.—

6 (1) IN GENERAL.—A group health plan, and a
7 health insurance issuer that provides health insur-
8 ance coverage, shall conduct utilization review activi-
9 ties in connection with the provision of benefits
10 under such plan or coverage only in accordance with
11 a utilization review program that meets the require-
12 ments of this section.

1 (2) USE OF OUTSIDE AGENTS.—Nothing in this
2 section shall be construed as preventing a group
3 health plan or health insurance issuer from arrang-
4 ing through a contract or otherwise for persons or
5 entities to conduct utilization review activities on be-
6 half of the plan or issuer, so long as such activities
7 are conducted in accordance with a utilization review
8 program that meets the requirements of this section.

9 (3) UTILIZATION REVIEW DEFINED.—For pur-
10 poses of this section, the terms “utilization review”
11 and “utilization review activities” mean procedures
12 used to monitor or evaluate the use or coverage,
13 clinical necessity, appropriateness, efficacy, or effi-
14 ciency of health care services, procedures or settings,
15 and includes prospective review, concurrent review,
16 second opinions, case management, discharge plan-
17 ning, or retrospective review.

18 (b) WRITTEN POLICIES AND CRITERIA.—

19 (1) WRITTEN POLICIES.—A utilization review
20 program shall be conducted consistent with written
21 policies and procedures that govern all aspects of the
22 program.

23 (2) USE OF WRITTEN CRITERIA.—

24 (A) IN GENERAL.—Such a program shall
25 utilize written clinical review criteria developed

1 with input from a range of appropriate actively
2 practicing health care professionals, as deter-
3 mined by the plan, pursuant to the program.
4 Such criteria shall include written clinical re-
5 view criteria that are based on valid clinical evi-
6 dence where available and that are directed spe-
7 cifically at meeting the needs of at-risk popu-
8 lations and covered individuals with chronic
9 conditions or severe illnesses, including gender-
10 specific criteria and pediatric-specific criteria
11 where available and appropriate.

12 (B) CONTINUING USE OF STANDARDS IN
13 RETROSPECTIVE REVIEW.—If a health care
14 service has been specifically pre-authorized or
15 approved for an enrollee under such a program,
16 the program shall not, pursuant to retrospective
17 review, revise or modify the specific standards,
18 criteria, or procedures used for the utilization
19 review for procedures, treatment, and services
20 delivered to the enrollee during the same course
21 of treatment.

22 (C) REVIEW OF SAMPLE OF CLAIMS DENI-
23 ALS.—Such a program shall provide for an
24 evaluation of the clinical appropriateness of at
25 least a sample of denials of claims for benefits.

1 (c) CONDUCT OF PROGRAM ACTIVITIES.—

2 (1) ADMINISTRATION BY HEALTH CARE PRO-
 3 FESSIOALS.—A utilization review program shall be
 4 administered by qualified health care professionals
 5 who shall oversee review decisions.

6 (2) USE OF QUALIFIED, INDEPENDENT PER-
 7 SONNEL.—

8 (A) IN GENERAL.—A utilization review
 9 program shall provide for the conduct of utiliza-
 10 tion review activities only through personnel
 11 who are qualified and have received appropriate
 12 training in the conduct of such activities under
 13 the program.

14 (B) PROHIBITION OF CONTINGENT COM-
 15 PENSATION ARRANGEMENTS.—Such a program
 16 shall not, with respect to utilization review ac-
 17 tivities, permit or provide compensation or any-
 18 thing of value to its employees, agents, or con-
 19 tractors in a manner that encourages denials of
 20 claims for benefits.

21 (C) PROHIBITION OF CONFLICTS.—Such a
 22 program shall not permit a health care profes-
 23 sional who is providing health care services to
 24 an individual to perform utilization review ac-

1 activities in connection with the health care serv-
 2 ices being provided to the individual.

3 (3) ACCESSIBILITY OF REVIEW.—Such a pro-
 4 gram shall provide that appropriate personnel per-
 5 forming utilization review activities under the pro-
 6 gram, including the utilization review administrator,
 7 are reasonably accessible by toll-free telephone dur-
 8 ing normal business hours to discuss patient care
 9 and allow response to telephone requests, and that
 10 appropriate provision is made to receive and respond
 11 promptly to calls received during other hours.

12 (4) LIMITS ON FREQUENCY.—Such a program
 13 shall not provide for the performance of utilization
 14 review activities with respect to a class of services
 15 furnished to an individual more frequently than is
 16 reasonably required to assess whether the services
 17 under review are medically necessary or appropriate.

18 (d) DEADLINE FOR DETERMINATIONS.—

19 (1) PRIOR AUTHORIZATION SERVICES.—

20 (A) IN GENERAL.—Except as provided in
 21 paragraph (2), in the case of a utilization re-
 22 view activity involving the prior authorization of
 23 health care items and services for an individual,
 24 the utilization review program shall make a de-
 25 termination concerning such authorization, and

1 provide notice of the determination to the indi-
 2 vidual or the individual's designee and the indi-
 3 vidual's health care provider by telephone and
 4 in printed form, as soon as possible in accord-
 5 ance with the medical exigencies of the case,
 6 and in no event later than the deadline specified
 7 in subparagraph (B).

8 (B) DEADLINE.—

9 (i) IN GENERAL.—Subject to clauses
 10 (ii) and (iii), the deadline specified in this
 11 subparagraph is 14 days after the date of
 12 receipt of the request for prior authoriza-
 13 tion.

14 (ii) EXTENSION PERMITTED WHERE
 15 NOTICE OF ADDITIONAL INFORMATION RE-
 16 QUIRED.—If a utilization review
 17 program—

18 (I) receives a request for a prior
 19 authorization;

20 (II) determines that additional
 21 information is necessary to complete
 22 the review and make the determina-
 23 tion on the request; and

24 (III) notifies the requester, not
 25 later than five business days after the

1 date of receiving the request, of the
 2 need for such specified additional in-
 3 formation,

4 the deadline specified in this subparagraph
 5 is 14 days after the date the program re-
 6 ceives the specified additional information,
 7 but in no case later than 28 days after the
 8 date of receipt of the request for the prior
 9 authorization. This clause shall not apply
 10 if the deadline is specified in clause (iii).

11 (iii) EXPEDITED CASES.—In the case
 12 of a situation described in section
 13 102(c)(1)(A), the deadline specified in this
 14 subparagraph is 72 hours after the time of
 15 the request for prior authorization.

16 (2) ONGOING CARE.—

17 (A) CONCURRENT REVIEW.—

18 (i) IN GENERAL.—Subject to subpara-
 19 graph (B), in the case of a concurrent re-
 20 view of ongoing care (including hospitaliza-
 21 tion), which results in a termination or re-
 22 duction of such care, the plan must provide
 23 by telephone and in printed form notice of
 24 the concurrent review determination to the
 25 individual or the individual's designee and

1 the individual's health care provider as
 2 soon as possible in accordance with the
 3 medical exigencies of the case, with suffi-
 4 cient time prior to the termination or re-
 5 duction to allow for an appeal under sec-
 6 tion 102(c)(1)(A) to be completed before
 7 the termination or reduction takes effect.

8 (ii) CONTENTS OF NOTICE.—Such no-
 9 tice shall include, with respect to ongoing
 10 health care items and services, the number
 11 of ongoing services approved, the new total
 12 of approved services, the date of onset of
 13 services, and the next review date, if any,
 14 as well as a statement of the individual's
 15 rights to further appeal.

16 (B) EXCEPTION.—Subparagraph (A) shall
 17 not be interpreted as requiring plans or issuers
 18 to provide coverage of care that would exceed
 19 the coverage limitations for such care.

20 (3) PREVIOUSLY PROVIDED SERVICES.—In the
 21 case of a utilization review activity involving retro-
 22 spective review of health care services previously pro-
 23 vided for an individual, the utilization review pro-
 24 gram shall make a determination concerning such
 25 services, and provide notice of the determination to

1 the individual or the individual's designee and the
2 individual's health care provider by telephone and in
3 printed form, within 30 days of the date of receipt
4 of information that is reasonably necessary to make
5 such determination, but in no case later than 60
6 days after the date of receipt of the claim for bene-
7 fits.

8 (4) FAILURE TO MEET DEADLINE.—In a case
9 in which a group health plan or health insurance
10 issuer fails to make a determination on a claim for
11 benefit under paragraph (1), (2)(A), or (3) by the
12 applicable deadline established under the respective
13 paragraph, the failure shall be treated under this
14 subtitle as a denial of the claim as of the date of the
15 deadline.

16 (5) REFERENCE TO SPECIAL RULES FOR EMER-
17 GENCY SERVICES, MAINTENANCE CARE, AND POST-
18 STABILIZATION CARE.—For waiver of prior author-
19 ization requirements in certain cases involving emer-
20 gency services and maintenance care and post-sta-
21 bilization care, see subsections (a)(1) and (b) of sec-
22 tion 113, respectively.

23 (e) NOTICE OF DENIALS OF CLAIMS FOR BENE-
24 FITS.—

1 (1) IN GENERAL.—Notice of a denial of claims
 2 for benefits under a utilization review program shall
 3 be provided in printed form and written in a manner
 4 calculated to be understood by the participant, bene-
 5 ficiary, or enrollee and shall include—

6 (A) the reasons for the denial (including
 7 the clinical rationale);

8 (B) instructions on how to initiate an ap-
 9 peal under section 102; and

10 (C) notice of the availability, upon request
 11 of the individual (or the individual’s designee)
 12 of the clinical review criteria relied upon to
 13 make such denial.

14 (2) SPECIFICATION OF ANY ADDITIONAL INFOR-
 15 MATION.—Such a notice shall also specify what (if
 16 any) additional necessary information must be pro-
 17 vided to, or obtained by, the person making the de-
 18 nial in order to make a decision on such an appeal.

19 (f) CLAIM FOR BENEFITS AND DENIAL OF CLAIM
 20 FOR BENEFITS DEFINED.—For purposes of this subtitle:

21 (1) CLAIM FOR BENEFITS.—The term “claim
 22 for benefits” means any request for coverage (in-
 23 cluding authorization of coverage), for eligibility, or
 24 for payment in whole or in part, for an item or serv-

1 ice under a group health plan or health insurance
2 coverage.

3 (2) DENIAL OF CLAIM FOR BENEFITS.—The
4 term “denial” means, with respect to a claim for
5 benefits, a denial, or a failure to act on a timely
6 basis upon, in whole or in part, the claim for bene-
7 fits and includes a failure to provide benefits (in-
8 cluding items and services) required to be provided
9 under this title.

10 **SEC. 102. INTERNAL APPEALS PROCEDURES.**

11 (a) RIGHT OF REVIEW.—

12 (1) IN GENERAL.—Each group health plan, and
13 each health insurance issuer offering health insur-
14 ance coverage—

15 (A) shall provide adequate notice in writ-
16 ing to any participant or beneficiary under such
17 plan, or enrollee under such coverage, whose
18 claim for benefits under the plan or coverage
19 has been denied (within the meaning of section
20 101(f)(2)), setting forth the specific reasons for
21 such denial of claim for benefits and rights to
22 any further review or appeal, written in a man-
23 ner calculated to be understood by the partici-
24 pant, beneficiary, or enrollee; and

(B) shall afford such a participant, beneficiary, or enrollee (and any provider or other person acting on behalf of such an individual with the individual's consent or without such consent if the individual is medically unable to provide such consent) who is dissatisfied with such a denial of claim for benefits a reasonable opportunity (of not less than 180 days) to request and obtain a full and fair review by a named fiduciary (with respect to such plan) or named appropriate individual (with respect to such coverage) of the decision denying the claim.

(2) TREATMENT OF ORAL REQUESTS.—The request for review under paragraph (1)(B) may be made orally, but, in the case of an oral request, shall be followed by a request in writing.

(b) INTERNAL REVIEW PROCESS.—

(1) CONDUCT OF REVIEW.—

(A) IN GENERAL.—A review of a denial of claim under this section shall be made by an individual who—

(i) in a case involving medical judgment, shall be a physician or, in the case of limited scope coverage (as defined in

1 subparagraph (B)), shall be an appropriate
2 specialist;

3 (ii) has been selected by the plan or
4 issuer; and

5 (iii) did not make the initial denial in
6 the internally appealable decision.

7 (B) LIMITED SCOPE COVERAGE DE-
8 FINED.—For purposes of subparagraph (A), the
9 term “limited scope coverage” means a group
10 health plan or health insurance coverage the
11 only benefits under which are for benefits de-
12 scribed in section 2791(c)(2)(A) of the Public
13 Health Service Act (42 U.S.C. 300gg–91(c)(2)).

14 (2) TIME LIMITS FOR INTERNAL REVIEWS.—

15 (A) IN GENERAL.—Having received such a
16 request for review of a denial of claim, the plan
17 or issuer shall, in accordance with the medical
18 exigencies of the case but not later than the
19 deadline specified in subparagraph (B), com-
20 plete the review on the denial and transmit to
21 the participant, beneficiary, enrollee, or other
22 person involved a decision that affirms, re-
23 verses, or modifies the denial. If the decision
24 does not reverse the denial, the plan or issuer
25 shall transmit, in printed form, a notice that

1 sets forth the grounds for such decision and
2 that includes a description of rights to any fur-
3 ther appeal. Such decision shall be treated as
4 the final decision of the plan. Failure to issue
5 such a decision by such deadline shall be treat-
6 ed as a final decision affirming the denial of
7 claim.

8 (B) DEADLINE.—

9 (i) IN GENERAL.—Subject to clauses
10 (ii) and (iii), the deadline specified in this
11 subparagraph is 14 days after the date of
12 receipt of the request for internal review.

13 (ii) EXTENSION PERMITTED WHERE
14 NOTICE OF ADDITIONAL INFORMATION RE-
15 QUIRED.—If a group health plan or health
16 insurance issuer—

17 (I) receives a request for internal
18 review;

19 (II) determines that additional
20 information is necessary to complete
21 the review and make the determina-
22 tion on the request; and

23 (III) notifies the requester, not
24 later than five business days after the
25 date of receiving the request, of the

1 need for such specified additional in-
 2 formation,
 3 the deadline specified in this subparagraph
 4 is 14 days after the date the plan or issuer
 5 receives the specified additional informa-
 6 tion, but in no case later than 28 days
 7 after the date of receipt of the request for
 8 the internal review. This clause shall not
 9 apply if the deadline is specified in clause
 10 (iii).

11 (iii) EXPEDITED CASES.—In the case
 12 of a situation described in subsection
 13 (c)(1)(A), the deadline specified in this
 14 subparagraph is 72 hours after the time of
 15 the request for review.

16 (c) EXPEDITED REVIEW PROCESS.—

17 (1) IN GENERAL.—A group health plan, and a
 18 health insurance issuer, shall establish procedures in
 19 writing for the expedited consideration of requests
 20 for review under subsection (b) in situations—

21 (A) in which the application of the normal
 22 timeframe for making a determination could se-
 23 riously jeopardize the life or health of the par-
 24 ticipant, beneficiary, or enrollee or such an indi-
 25 vidual's ability to regain maximum function; or

1 (B) described in section 101(d)(2) (relat-
2 ing to requests for continuation of ongoing care
3 which would otherwise be reduced or termi-
4 nated).

5 (2) PROCESS.—Under such procedures—

6 (A) the request for expedited review may
7 be submitted orally or in writing by an indi-
8 vidual or provider who is otherwise entitled to
9 request the review;

10 (B) all necessary information, including
11 the plan's or issuer's decision, shall be trans-
12 mitted between the plan or issuer and the re-
13 quester by telephone, facsimile, or other simi-
14 larly expeditious available method; and

15 (C) the plan or issuer shall expedite the re-
16 view in the case of any of the situations de-
17 scribed in subparagraph (A) or (B) of para-
18 graph (1).

19 (3) DEADLINE FOR DECISION.—The decision on
20 the expedited review must be made and commu-
21 nicated to the parties as soon as possible in accord-
22 ance with the medical exigencies of the case, and in
23 no event later than 72 hours after the time of re-
24 ceipt of the request for expedited review, except that
25 in a case described in paragraph (1)(B), the decision

1 must be made before the end of the approved period
 2 of care.

3 (d) WAIVER OF PROCESS.—A plan or issuer may
 4 waive its rights for an internal review under subsection
 5 (b). In such case the participant, beneficiary, or enrollee
 6 involved (and any designee or provider involved) shall be
 7 relieved of any obligation to complete the review involved
 8 and may, at the option of such participant, beneficiary,
 9 enrollee, designee, or provider, proceed directly to seek
 10 further appeal through any applicable external appeals
 11 process.

12 **SEC. 103. EXTERNAL APPEALS PROCEDURES.**

13 (a) RIGHT TO EXTERNAL APPEAL.—

14 (1) IN GENERAL.—A group health plan, and a
 15 health insurance issuer offering health insurance
 16 coverage, shall provide for an external appeals proc-
 17 ess that meets the requirements of this section in
 18 the case of an externally appealable decision de-
 19 scribed in paragraph (2), for which a timely appeal
 20 is made either by the plan or issuer or by the partic-
 21 ipant, beneficiary, or enrollee (and any provider or
 22 other person acting on behalf of such an individual
 23 with the individual's consent or without such consent
 24 if such an individual is medically unable to provide

1 such consent). The appropriate Secretary shall es-
 2 tablish standards to carry out such requirements.

3 (2) EXTERNALLY APPEALABLE DECISION DE-
 4 FINED.—

5 (A) IN GENERAL.—For purposes of this
 6 section, the term “externally appealable deci-
 7 sion” means a denial of claim for benefits (as
 8 defined in section 101(f)(2))—

9 (i) that is based in whole or in part on
 10 a decision that the item or service is not
 11 medically necessary or appropriate or is in-
 12 vestigational or experimental; or

13 (ii) in which the decision as to wheth-
 14 er a benefit is covered involves a medical
 15 judgment.

16 (B) INCLUSION.—Such term also includes
 17 a failure to meet an applicable deadline for in-
 18 ternal review under section 102.

19 (C) EXCLUSIONS.—Such term does not
 20 include—

21 (i) specific exclusions or express limi-
 22 tations on the amount, duration, or scope
 23 of coverage that do not involve medical
 24 judgment; or

1 (ii) a decision regarding whether an
2 individual is a participant, beneficiary, or
3 enrollee under the plan or coverage.

4 (3) EXHAUSTION OF INTERNAL REVIEW PROC-
5 ESS.—Except as provided under section 102(d), a
6 plan or issuer may condition the use of an external
7 appeal process in the case of an externally appeal-
8 able decision upon a final decision in an internal re-
9 view under section 102, but only if the decision is
10 made in a timely basis consistent with the deadlines
11 provided under this subtitle.

12 (4) FILING FEE REQUIREMENT.—

13 (A) IN GENERAL.—Subject to subpara-
14 graph (B), a plan or issuer may condition the
15 use of an external appeal process upon payment
16 to the plan or issuer of a filing fee that does
17 not exceed \$25.

18 (B) EXCEPTION FOR INDIGENCY.—The
19 plan or issuer may not require payment of the
20 filing fee in the case of an individual partici-
21 pant, beneficiary, or enrollee who certifies (in a
22 form and manner specified in guidelines estab-
23 lished by the Secretary of Health and Human
24 Services) that the individual is indigent (as de-
25 fined in such guidelines).

1 (C) REFUNDING FEE IN CASE OF SUCCESS-
 2 FUL APPEALS.—The plan or issuer shall refund
 3 payment of the filing fee under this paragraph
 4 if the recommendation of the external appeal
 5 entity is to reverse or modify the denial of a
 6 claim for benefits which is the subject of the
 7 appeal.

8 (b) GENERAL ELEMENTS OF EXTERNAL APPEALS
 9 PROCESS.—

10 (1) CONTRACT WITH QUALIFIED EXTERNAL AP-
 11 PEAL ENTITY.—

12 (A) CONTRACT REQUIREMENT.—Except as
 13 provided in subparagraph (D), the external ap-
 14 peal process under this section of a plan or
 15 issuer shall be conducted under a contract be-
 16 tween the plan or issuer and one or more quali-
 17 fied external appeal entities (as defined in sub-
 18 section (c)).

19 (B) LIMITATION ON PLAN OR ISSUER SE-
 20 LECTION.—

21 (i) IN GENERAL.—The applicable au-
 22 thority shall implement procedures—

23 (I) to assure that the selection
 24 process among qualified external ap-
 25 peal entities will not create any incen-

1 tives for external appeal entities to
 2 make a decision in a biased manner;
 3 and

4 (II) for auditing a sample of de-
 5 cisions by such entities to assure that
 6 no such decisions are made in a bi-
 7 ased manner.

8 (ii) LIMITATION ON ABILITY TO IN-
 9 FLUENCE SELECTION.—No selection proc-
 10 ess established by the applicable authority
 11 under this subsection shall provide the par-
 12 ticipant, beneficiary, or enrollee or the plan
 13 or issuer with the ability to determine or
 14 influence the selection of a qualified exter-
 15 nal appeal entity to review the appeal of
 16 the participant, beneficiary, or enrollee.

17 (C) OTHER TERMS AND CONDITIONS.—
 18 The terms and conditions of a contract under
 19 this paragraph shall be consistent with the
 20 standards the appropriate Secretary shall estab-
 21 lish to assure there is no real or apparent con-
 22 flict of interest in the conduct of external ap-
 23 peal activities. Such contract shall provide that
 24 all costs of the process (except those incurred
 25 by the participant, beneficiary, enrollee, or

treating professional in support of the appeal) shall be paid by the plan or issuer, and not by the participant, beneficiary, or enrollee. The previous sentence shall not be construed as applying to the imposition of a filing fee under subsection (a)(4).

(D) STATE AUTHORITY WITH RESPECT TO QUALIFIED EXTERNAL APPEAL ENTITY FOR HEALTH INSURANCE ISSUERS.—With respect to health insurance issuers offering health insurance coverage in a State, the State may provide for external review activities to be conducted by a qualified external appeal entity that is designated by the State or that is selected by the State in a manner determined by the State to assure an unbiased determination.

(2) ELEMENTS OF PROCESS.—An external appeal process shall be conducted consistent with standards established by the appropriate Secretary that include at least the following:

(A) FAIR AND DE NOVO DETERMINATION.—The process shall provide for a fair, de novo determination. However, nothing in this paragraph shall be construed as providing for coverage of items and services for which bene-

fits are specifically excluded under the plan or coverage.

(B) STANDARD OF REVIEW.—An external appeal entity shall determine whether the plan’s or issuer’s decision is in accordance with the medical needs of the patient involved (as determined by the entity) taking into account, as of the time of the entity’s determination, the patient’s medical condition and any relevant and reliable evidence the entity obtains under subparagraph (D). If the entity determines the decision is in accordance with such needs, the entity shall affirm the decision and to the extent that the entity determines the decision is not in accordance with such needs, the entity shall reverse or modify the decision.

(C) CONSIDERATION OF PLAN OR COVERAGE DEFINITIONS.—In making such determination, the external appeal entity shall consider (but not be bound by) any language in the plan or coverage document relating to the definitions of the terms medical necessity, medically necessary or appropriate, or experimental, investigational, or related terms.

(D) EVIDENCE.—

1 (i) IN GENERAL.—An external appeal
2 entity shall include, among the evidence
3 taken into consideration—

4 (I) the decision made by the plan
5 or issuer upon internal review under
6 section 102 and any guidelines or
7 standards used by the plan or issuer
8 in reaching such decision;

9 (II) any personal health and
10 medical information supplied with re-
11 spect to the individual whose denial of
12 claim for benefits has been appealed;
13 and

14 (III) the opinion of the individ-
15 ual's treating physician or health care
16 professional.

17 (ii) ADDITIONAL EVIDENCE.—Such
18 entity may also take into consideration but
19 not be limited to the following evidence (to
20 the extent available):

21 (I) The results of studies that
22 meet professionally recognized stand-
23 ards of validity and replicability or
24 that have been published in peer-re-
25 viewed journals.

1 (II) The results of professional
2 consensus conferences conducted or fi-
3 nanced in whole or in part by one or
4 more Government agencies.

5 (III) Practice and treatment
6 guidelines prepared or financed in
7 whole or in part by Government agen-
8 cies.

9 (IV) Government-issued coverage
10 and treatment policies.

11 (V) Community standard of care
12 and generally accepted principles of
13 professional medical practice.

14 (VI) To the extent that the entity
15 determines it to be free of any conflict
16 of interest, the opinions of individuals
17 who are qualified as experts in one or
18 more fields of health care which are
19 directly related to the matters under
20 appeal.

21 (VII) To the extent that the enti-
22 ty determines it to be free of any con-
23 flict of interest, the results of peer re-
24 views conducted by the plan or issuer
25 involved.

1 (E) DETERMINATION CONCERNING EXTER-
 2 NALLY APPEALABLE DECISIONS.—A qualified
 3 external appeal entity shall determine—

4 (i) whether a denial of claim for bene-
 5 fits is an externally appealable decision
 6 (within the meaning of subsection (a)(2));

7 (ii) whether an externally appealable
 8 decision involves an expedited appeal; and

9 (iii) for purposes of initiating an ex-
 10 ternal review, whether the internal review
 11 process has been completed.

12 (F) OPPORTUNITY TO SUBMIT EVI-
 13 DENCE.—Each party to an externally appeal-
 14 able decision may submit evidence related to the
 15 issues in dispute.

16 (G) PROVISION OF INFORMATION.—The
 17 plan or issuer involved shall provide timely ac-
 18 cess to the external appeal entity to information
 19 and to provisions of the plan or health insur-
 20 ance coverage relating to the matter of the ex-
 21 ternally appealable decision, as determined by
 22 the entity.

23 (H) TIMELY DECISIONS.—A determination
 24 by the external appeal entity on the decision
 25 shall—

1 (i) be made orally or in writing and,
2 if it is made orally, shall be supplied to the
3 parties in writing as soon as possible;

4 (ii) be made in accordance with the
5 medical exigencies of the case involved, but
6 in no event later than 21 days after the
7 date (or, in the case of an expedited ap-
8 peal, 72 hours after the time) of requesting
9 an external appeal of the decision;

10 (iii) state, in layperson's language, the
11 basis for the determination, including, if
12 relevant, any basis in the terms or condi-
13 tions of the plan or coverage; and

14 (iv) inform the participant, bene-
15 ficiary, or enrollee of the individual's rights
16 (including any limitation on such rights) to
17 seek further review by the courts (or other
18 process) of the external appeal determina-
19 tion.

20 (I) COMPLIANCE WITH DETERMINATION.—

21 If the external appeal entity reverses or modi-
22 fies the denial of a claim for benefits, the plan
23 or issuer shall—

1 (i) upon the receipt of the determina-
 2 tion, authorize benefits in accordance with
 3 such determination;

4 (ii) take such actions as may be nec-
 5 essary to provide benefits (including items
 6 or services) in a timely manner consistent
 7 with such determination; and

8 (iii) submit information to the entity
 9 documenting compliance with the entity's
 10 determination and this subparagraph.

11 (c) QUALIFICATIONS OF EXTERNAL APPEAL ENTI-
 12 TIES.—

13 (1) IN GENERAL.—For purposes of this section,
 14 the term “qualified external appeal entity” means,
 15 in relation to a plan or issuer, an entity that is cer-
 16 tified under paragraph (2) as meeting the following
 17 requirements:

18 (A) The entity meets the independence re-
 19 quirements of paragraph (3).

20 (B) The entity conducts external appeal
 21 activities through a panel of not fewer than
 22 three clinical peers.

23 (C) The entity has sufficient medical, legal,
 24 and other expertise and sufficient staffing to
 25 conduct external appeal activities for the plan

1 or issuer on a timely basis consistent with sub-
 2 section (b)(2)(G).

3 (D) The entity meets such other require-
 4 ments as the appropriate Secretary may im-
 5 pose.

6 (2) INITIAL CERTIFICATION OF EXTERNAL AP-
 7 PEAL ENTITIES.—

8 (A) IN GENERAL.—In order to be treated
 9 as a qualified external appeal entity with re-
 10 spect to—

11 (i) a group health plan, the entity
 12 must be certified (and, in accordance with
 13 subparagraph (B), periodically recertified)
 14 as meeting the requirements of paragraph
 15 (1)—

16 (I) by the Secretary of Labor;

17 (II) under a process recognized
 18 or approved by the Secretary of
 19 Labor; or

20 (III) to the extent provided in
 21 subparagraph (C)(i), by a qualified
 22 private standard-setting organization
 23 (certified under such subparagraph);
 24 or

(ii) a health insurance issuer operating in a State, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting such requirements—

(I) by the applicable State authority (or under a process recognized or approved by such authority); or

(II) if the State has not established a certification and recertification process for such entities, by the Secretary of Health and Human Services, under a process recognized or approved by such Secretary, or to the extent provided in subparagraph (C)(ii), by a qualified private standard-setting organization (certified under such subparagraph).

(B) RECERTIFICATION PROCESS.—The appropriate Secretary shall develop standards for the recertification of external appeal entities. Such standards shall include a review of—

(i) the number of cases reviewed;

(ii) a summary of the disposition of those cases;

1 (iii) the length of time in making de-
 2 terminations on those cases;

3 (iv) updated information of what was
 4 required to be submitted as a condition of
 5 certification for the entity's performance of
 6 external appeal activities; and

7 (v) such information as may be nec-
 8 essary to assure the independence of the
 9 entity from the plans or issuers for which
 10 external appeal activities are being con-
 11 ducted.

12 (C) CERTIFICATION OF QUALIFIED PRI-
 13 VATE STANDARD-SETTING ORGANIZATIONS.—

14 (i) FOR EXTERNAL REVIEWS UNDER
 15 GROUP HEALTH PLANS.—For purposes of
 16 subparagraph (A)(i)(III), the Secretary of
 17 Labor may provide for a process for certifi-
 18 cation (and periodic recertification) of
 19 qualified private standard-setting organiza-
 20 tions which provide for certification of ex-
 21 ternal review entities. Such an organization
 22 shall only be certified if the organization
 23 does not certify an external review entity
 24 unless it meets standards required for cer-

1 tification of such an entity by such Sec-
 2 retary under subparagraph (A)(i)(I).

3 (ii) FOR EXTERNAL REVIEWS OF
 4 HEALTH INSURANCE ISSUERS.—For pur-
 5 poses of subparagraph (A)(ii)(II), the Sec-
 6 retary of Health and Human Services may
 7 provide for a process for certification (and
 8 periodic recertification) of qualified private
 9 standard-setting organizations which pro-
 10 vide for certification of external review en-
 11 tities. Such an organization shall only be
 12 certified if the organization does not certify
 13 an external review entity unless it meets
 14 standards required for certification of such
 15 an entity by such Secretary under subpara-
 16 graph (A)(ii)(II).

17 (D) REQUIREMENT OF SUFFICIENT NUM-
 18 BER OF CERTIFIED ENTITIES.—The appro-
 19 priate Secretary shall certify and recertify a
 20 sufficient number of external appeal entities
 21 under this paragraph to ensure the timely and
 22 efficient provision of external review services.

23 (3) INDEPENDENCE REQUIREMENTS.—

1 (A) IN GENERAL.—A clinical peer or other
 2 entity meets the independence requirements of
 3 this paragraph if—

4 (i) the peer or entity does not have a
 5 familial, financial, or professional relation-
 6 ship with any related party;

7 (ii) any compensation received by such
 8 peer or entity in connection with the exter-
 9 nal review is reasonable and not contingent
 10 on any decision rendered by the peer or en-
 11 tity;

12 (iii) except as provided in paragraph
 13 (4), the plan and the issuer have no re-
 14 course against the peer or entity in connec-
 15 tion with the external review; and

16 (iv) the peer or entity does not other-
 17 wise have a conflict of interest with a re-
 18 lated party as determined under any regu-
 19 lations which the Secretary may prescribe.

20 (B) RELATED PARTY.—For purposes of
 21 this paragraph, the term “related party”
 22 means—

23 (i) with respect to—

24 (I) a group health plan or health
 25 insurance coverage offered in connec-

1 tion with such a plan, the plan or the
 2 health insurance issuer offering such
 3 coverage; or

4 (II) individual health insurance
 5 coverage, the health insurance issuer
 6 offering such coverage,

7 or any plan sponsor, fiduciary, officer, di-
 8 rector, or management employee of such
 9 plan or issuer;

10 (ii) the health care professional that
 11 provided the health care involved in the
 12 coverage decision;

13 (iii) the institution at which the health
 14 care involved in the coverage decision is
 15 provided;

16 (iv) the manufacturer of any drug or
 17 other item that was included in the health
 18 care involved in the coverage decision; or

19 (v) any other party determined under
 20 any regulations which the Secretary may
 21 prescribe to have a substantial interest in
 22 the coverage decision.

23 (4) LIMITATION ON LIABILITY OF REVIEW-
 24 ERS.—No qualified external appeal entity having a
 25 contract with a plan or issuer under this part and

1 no person who is employed by any such entity or
 2 who furnishes professional services to such entity,
 3 shall be held by reason of the performance of any
 4 duty, function, or activity required or authorized
 5 pursuant to this section, to have violated any crimi-
 6 nal law, or to be civilly liable under any law of the
 7 United States or of any State (or political subdivi-
 8 sion thereof) if due care was exercised in the per-
 9 formance of such duty, function, or activity and
 10 there was no actual malice or gross misconduct in
 11 the performance of such duty, function, or activity.

12 (d) EXTERNAL APPEAL DETERMINATION BINDING
 13 ON PLAN.—The determination by an external appeal enti-
 14 ty under this section is binding on the plan and issuer
 15 involved in the determination.

16 (e) PENALTIES AGAINST AUTHORIZED OFFICIALS
 17 FOR REFUSING TO AUTHORIZE THE DETERMINATION OF
 18 AN EXTERNAL REVIEW ENTITY.—

19 (1) MONETARY PENALTIES.—In any case in
 20 which the determination of an external review entity
 21 is not followed by a group health plan, or by a
 22 health insurance issuer offering health insurance
 23 coverage, any person who, acting in the capacity of
 24 authorizing the benefit, causes such refusal may, in
 25 the discretion in a court of competent jurisdiction,

1 be liable to an aggrieved participant, beneficiary, or
 2 enrollee for a civil penalty in an amount of up to
 3 \$1,000 a day from the date on which the determina-
 4 tion was transmitted to the plan or issuer by the ex-
 5 ternal review entity until the date the refusal to pro-
 6 vide the benefit is corrected.

7 (2) CEASE AND DESIST ORDER AND ORDER OF
 8 ATTORNEY'S FEES.—In any action described in
 9 paragraph (1) brought by a participant, beneficiary,
 10 or enrollee with respect to a group health plan, or
 11 a health insurance issuer offering health insurance
 12 coverage, in which a plaintiff alleges that a person
 13 referred to in such paragraph has taken an action
 14 resulting in a refusal of a benefit determined by an
 15 external appeal entity in violation of such terms of
 16 the plan, coverage, or this subtitle, or has failed to
 17 take an action for which such person is responsible
 18 under the plan, coverage, or this title and which is
 19 necessary under the plan or coverage for authorizing
 20 a benefit, the court shall cause to be served on the
 21 defendant an order requiring the defendant—

22 (A) to cease and desist from the alleged
 23 action or failure to act; and

24 (B) to pay to the plaintiff a reasonable at-
 25 torney's fee and other reasonable costs relating

1 to the prosecution of the action on the charges
 2 on which the plaintiff prevails.

3 (3) ADDITIONAL CIVIL PENALTIES.—

4 (A) IN GENERAL.—In addition to any pen-
 5 alty imposed under paragraph (1) or (2), the
 6 appropriate Secretary may assess a civil penalty
 7 against a person acting in the capacity of au-
 8 thorizing a benefit determined by an external
 9 review entity for one or more group health
 10 plans, or health insurance issuers offering
 11 health insurance coverage, for—

12 (i) any pattern or practice of repeated
 13 refusal to authorize a benefit determined
 14 by an external appeal entity in violation of
 15 the terms of such a plan, coverage, or this
 16 title; or

17 (ii) any pattern or practice of re-
 18 peated violations of the requirements of
 19 this section with respect to such plan or
 20 plans or coverage.

21 (B) STANDARD OF PROOF AND AMOUNT OF
 22 PENALTY.—Such penalty shall be payable only
 23 upon proof by clear and convincing evidence of
 24 such pattern or practice and shall be in an
 25 amount not to exceed the lesser of—

- 1 (i) 25 percent of the aggregate value
 2 of benefits shown by the appropriate Sec-
 3 retary to have not been provided, or unlaw-
 4 fully delayed, in violation of this section
 5 under such pattern or practice; or
 6 (ii) \$500,000.

7 (4) REMOVAL AND DISQUALIFICATION.—Any
 8 person acting in the capacity of authorizing benefits
 9 who has engaged in any such pattern or practice de-
 10 scribed in paragraph (3)(A) with respect to a plan
 11 or coverage, upon the petition of the appropriate
 12 Secretary, may be removed by the court from such
 13 position, and from any other involvement, with re-
 14 spect to such a plan or coverage, and may be pre-
 15 cluded from returning to any such position or in-
 16 volvement for a period determined by the court.

17 (f) PROTECTION OF LEGAL RIGHTS.—Nothing in
 18 this subtitle shall be construed as altering or eliminating
 19 any cause of action or legal rights or remedies of partici-
 20 pants, beneficiaries, enrollees, and others under State or
 21 Federal law (including sections 502 and 503 of the Em-
 22 ployee Retirement Income Security Act of 1974), includ-
 23 ing the right to file judicial actions to enforce rights.

24 **SEC. 104. ESTABLISHMENT OF A GRIEVANCE PROCESS.**

25 (a) ESTABLISHMENT OF GRIEVANCE SYSTEM.—

1 (1) IN GENERAL.—A group health plan, and a
2 health insurance issuer in connection with the provi-
3 sion of health insurance coverage, shall establish and
4 maintain a system to provide for the presentation
5 and resolution of oral and written grievances
6 brought by individuals who are participants, bene-
7 ficiaries, or enrollees, or health care providers or
8 other individuals acting on behalf of an individual
9 and with the individual’s consent or without such
10 consent if the individual is medically unable to pro-
11 vide such consent, regarding any aspect of the plan’s
12 or issuer’s services.

13 (2) GRIEVANCE DEFINED.—In this section, the
14 term “grievance” means any question, complaint, or
15 concern brought by a participant, beneficiary or en-
16 rollee that is not a claim for benefits (as defined in
17 section 101(f)(1)).

18 (b) GRIEVANCE SYSTEM.—Such system shall include
19 the following components with respect to individuals who
20 are participants, beneficiaries, or enrollees:

21 (1) Written notification to all such individuals
22 and providers of the telephone numbers and business
23 addresses of the plan or issuer personnel responsible
24 for resolution of grievances and appeals.

1 (2) A system to record and document, over a
2 period of at least three previous years, all grievances
3 and appeals made and their status.

4 (3) A process providing for timely processing
5 and resolution of grievances.

6 (4) Procedures for follow-up action, including
7 the methods to inform the person making the grievance
8 of the resolution of the grievance.

9 Grievances are not subject to appeal under the previous
10 provisions of this subtitle.

11 **Subtitle B—Access to Care**

12 **SEC. 111. CONSUMER CHOICE OPTION.**

13 (a) IN GENERAL.—If—

14 (1) a health insurance issuer providing health
15 insurance coverage in connection with a group health
16 plan offers to enrollees health insurance coverage
17 which provides for coverage of services only if such
18 services are furnished through health care profes-
19 sionals and providers who are members of a network
20 of health care professionals and providers who have
21 entered into a contract with the issuer to provide
22 such services, or

23 (2) a group health plan offers to participants or
24 beneficiaries health benefits which provide for cov-
25 erage of services only if such services are furnished

1 through health care professionals and providers who
2 are members of a network of health care profes-
3 sionals and providers who have entered into a con-
4 tract with the plan to provide such services,
5 then the issuer or plan shall also offer or arrange to be
6 offered to such enrollees, participants, or beneficiaries (at
7 the time of enrollment and during an annual open season
8 as provided under subsection (c)) the option of health in-
9 surance coverage or health benefits which provide for cov-
10 erage of such services which are not furnished through
11 health care professionals and providers who are members
12 of such a network unless such enrollees, participants, or
13 beneficiaries are offered such non-network coverage
14 through another group health plan or through another
15 health insurance issuer in the group market.

16 (b) ADDITIONAL COSTS.—The amount of any addi-
17 tional premium charged by the health insurance issuer or
18 group health plan for the additional cost of the creation
19 and maintenance of the option described in subsection (a)
20 and the amount of any additional cost sharing imposed
21 under such option shall be borne by the enrollee, partici-
22 pant, or beneficiary unless it is paid by the health plan
23 sponsor or group health plan through agreement with the
24 health insurance issuer.

1 (c) OPEN SEASON.—An enrollee, participant, or ben-
 2 eficiary, may change to the offering provided under this
 3 section only during a time period determined by the health
 4 insurance issuer or group health plan. Such time period
 5 shall occur at least annually.

6 **SEC. 112. CHOICE OF HEALTH CARE PROFESSIONAL.**

7 (a) PRIMARY CARE.—If a group health plan, or a
 8 health insurance issuer that offers health insurance cov-
 9 erage, requires or provides for designation by a partici-
 10 pant, beneficiary, or enrollee of a participating primary
 11 care provider, then the plan or issuer shall permit each
 12 participant, beneficiary, and enrollee to designate any par-
 13 ticipating primary care provider who is available to accept
 14 such individual.

15 (b) SPECIALISTS.—

16 (1) IN GENERAL.—Subject to paragraph (2), a
 17 group health plan and a health insurance issuer that
 18 offers health insurance coverage shall permit each
 19 participant, beneficiary, or enrollee to receive medi-
 20 cally necessary or appropriate specialty care, pursu-
 21 ant to appropriate referral procedures, from any
 22 qualified participating health care professional who
 23 is available to accept such individual for such care.

24 (2) LIMITATION.—Paragraph (1) shall not
 25 apply to specialty care if the plan or issuer clearly

1 informs participants, beneficiaries, and enrollees of
 2 the limitations on choice of participating health care
 3 professionals with respect to such care.

4 (3) CONSTRUCTION.—Nothing in this sub-
 5 section shall be construed as affecting the applica-
 6 tion of section 114 (relating to access to specialty
 7 care).

8 **SEC. 113. ACCESS TO EMERGENCY CARE.**

9 (a) COVERAGE OF EMERGENCY SERVICES.—

10 (1) IN GENERAL.—If a group health plan, or
 11 health insurance coverage offered by a health insur-
 12 ance issuer, provides any benefits with respect to
 13 services in an emergency department of a hospital,
 14 the plan or issuer shall cover emergency services (as
 15 defined in paragraph (2)(B))—

16 (A) without the need for any prior author-
 17 ization determination;

18 (B) whether or not the health care pro-
 19 vider furnishing such services is a participating
 20 provider with respect to such services;

21 (C) in a manner so that, if such services
 22 are provided to a participant, beneficiary, or
 23 enrollee—

1 (i) by a nonparticipating health care
 2 provider with or without prior authoriza-
 3 tion; or

4 (ii) by a participating health care pro-
 5 vider without prior authorization,
 6 the participant, beneficiary, or enrollee is not
 7 liable for amounts that exceed the amounts of
 8 liability that would be incurred if the services
 9 were provided by a participating health care
 10 provider with prior authorization; and

11 (D) without regard to any other term or
 12 condition of such coverage (other than exclusion
 13 or coordination of benefits, or an affiliation or
 14 waiting period, permitted under section 2701 of
 15 the Public Health Service Act, section 701 of
 16 the Employee Retirement Income Security Act
 17 of 1974, or section 9801 of the Internal Rev-
 18 enue Code of 1986, and other than applicable
 19 cost-sharing).

20 (2) DEFINITIONS.—In this section:

21 (A) EMERGENCY MEDICAL CONDITION
 22 BASED ON PRUDENT LAYPERSON STANDARD.—
 23 The term “emergency medical condition” means
 24 a medical condition manifesting itself by acute
 25 symptoms of sufficient severity (including se-

1 vere pain) such that a prudent layperson, who
2 possesses an average knowledge of health and
3 medicine, could reasonably expect the absence
4 of immediate medical attention to result in a
5 condition described in clause (i), (ii), or (iii) of
6 section 1867(e)(1)(A) of the Social Security
7 Act.

8 (B) EMERGENCY SERVICES.—The term
9 “emergency services” means—

10 (i) a medical screening examination
11 (as required under section 1867 of the So-
12 cial Security Act) that is within the capa-
13 bility of the emergency department of a
14 hospital, including ancillary services rou-
15 tinely available to the emergency depart-
16 ment to evaluate an emergency medical
17 condition (as defined in subparagraph
18 (A)); and

19 (ii) within the capabilities of the staff
20 and facilities available at the hospital, such
21 further medical examination and treatment
22 as are required under section 1867 of such
23 Act to stabilize the patient.

24 (C) STABILIZE.—The term “to stabilize”
25 means, with respect to an emergency medical

1 condition, to provide such medical treatment of
 2 the condition as may be necessary to assure,
 3 within reasonable medical probability, that no
 4 material deterioration of the condition is likely
 5 to result from or occur during the transfer of
 6 the individual from a facility.

7 (b) REIMBURSEMENT FOR MAINTENANCE CARE AND
 8 POST-STABILIZATION CARE.—In the case of services
 9 (other than emergency services) for which benefits are
 10 available under a group health plan, or under health insur-
 11 ance coverage offered by a health insurance issuer, the
 12 plan or issuer shall provide for reimbursement with re-
 13 spect to such services provided to a participant, bene-
 14 ficiary, or enrollee other than through a participating
 15 health care provider in a manner consistent with sub-
 16 section (a)(1)(C) (and shall otherwise comply with the
 17 guidelines established under section 1852(d)(2) of the So-
 18 cial Security Act), if the services are maintenance care or
 19 post-stabilization care covered under such guidelines.

20 **SEC. 114. ACCESS TO SPECIALTY CARE.**

21 (a) SPECIALTY CARE FOR COVERED SERVICES.—

22 (1) IN GENERAL.—If—

23 (A) an individual is a participant or bene-
 24 ficiary under a group health plan or an enrollee

1 who is covered under health insurance coverage
2 offered by a health insurance issuer;

3 (B) the individual has a condition or dis-
4 ease of sufficient seriousness and complexity to
5 require treatment by a specialist; and

6 (C) benefits for such treatment are pro-
7 vided under the plan or coverage,

8 the plan or issuer shall make or provide for a refer-
9 ral to a specialist who is available and accessible to
10 provide the treatment for such condition or disease.

11 (2) SPECIALIST DEFINED.—For purposes of
12 this subsection, the term “specialist” means, with
13 respect to a condition, a health care practitioner, fa-
14 cility, or center that has adequate expertise through
15 appropriate training and experience (including, in
16 the case of a child, appropriate pediatric expertise)
17 to provide high quality care in treating the condi-
18 tion.

19 (3) CARE UNDER REFERRAL.—A group health
20 plan or health insurance issuer may require that the
21 care provided to an individual pursuant to such re-
22 ferral under paragraph (1) be—

23 (A) pursuant to a treatment plan, only if
24 the treatment plan is developed by the specialist
25 and approved by the plan or issuer, in consulta-

tion with the designated primary care provider or specialist and the individual (or the individual's designee); and

(B) in accordance with applicable quality assurance and utilization review standards of the plan or issuer.

Nothing in this subsection shall be construed as preventing such a treatment plan for an individual from requiring a specialist to provide the primary care provider with regular updates on the specialty care provided, as well as all necessary medical information.

(4) REFERRALS TO PARTICIPATING PROVIDERS.—A group health plan or health insurance issuer is not required under paragraph (1) to provide for a referral to a specialist that is not a participating provider, unless the plan or issuer does not have an appropriate specialist that is available and accessible to treat the individual's condition and that is a participating provider with respect to such treatment.

(5) TREATMENT OF NONPARTICIPATING PROVIDERS.—If a plan or issuer refers an individual to a nonparticipating specialist pursuant to paragraph (1), services provided pursuant to the approved

1 treatment plan (if any) shall be provided at no addi-
2 tional cost to the individual beyond what the indi-
3 vidual would otherwise pay for services received by
4 such a specialist that is a participating provider.

5 (b) SPECIALISTS AS GATEKEEPER FOR TREATMENT
6 OF ONGOING SPECIAL CONDITIONS.—

7 (1) IN GENERAL.—A group health plan, or a
8 health insurance issuer, in connection with the provi-
9 sion of health insurance coverage, shall have a proce-
10 dure by which an individual who is a participant,
11 beneficiary, or enrollee and who has an ongoing spe-
12 cial condition (as defined in paragraph (3)) may re-
13 quest and receive a referral to a specialist for such
14 condition who shall be responsible for and capable of
15 providing and coordinating the individual's care with
16 respect to the condition. Under such procedures if
17 such an individual's care would most appropriately
18 be coordinated by such a specialist, such plan or
19 issuer shall refer the individual to such specialist.

20 (2) TREATMENT FOR RELATED REFERRALS.—

21 Such specialists shall be permitted to treat the indi-
22 vidual without a referral from the individual's pri-
23 mary care provider and may authorize such refer-
24 rals, procedures, tests, and other medical services as
25 the individual's primary care provider would other-

1 wise be permitted to provide or authorize, subject to
2 the terms of the treatment (referred to in subsection
3 (a)(3)(A)) with respect to the ongoing special condi-
4 tion.

5 (3) ONGOING SPECIAL CONDITION DEFINED.—

6 In this subsection, the term “ongoing special condi-
7 tion” means a condition or disease that—

8 (A) is life-threatening, degenerative, or dis-
9 abling; and

10 (B) requires specialized medical care over
11 a prolonged period of time.

12 (4) TERMS OF REFERRAL.—The provisions of
13 paragraphs (3) through (5) of subsection (a) apply
14 with respect to referrals under paragraph (1) of this
15 subsection in the same manner as they apply to re-
16 ferrals under subsection (a)(1).

17 (c) STANDING REFERRALS.—

18 (1) IN GENERAL.—A group health plan, and a
19 health insurance issuer in connection with the provi-
20 sion of health insurance coverage, shall have a proce-
21 dure by which an individual who is a participant,
22 beneficiary, or enrollee and who has a condition that
23 requires ongoing care from a specialist may receive
24 a standing referral to such specialist for treatment
25 of such condition. If the plan or issuer, or if the pri-

1 mary care provider in consultation with the medical
 2 director of the plan or issuer and the specialist (if
 3 any), determines that such a standing referral is ap-
 4 propriate, the plan or issuer shall make such a refer-
 5 ral to such a specialist if the individual so desires.

6 (2) TERMS OF REFERRAL.—The provisions of
 7 paragraphs (3) through (5) of subsection (a) apply
 8 with respect to referrals under paragraph (1) of this
 9 subsection in the same manner as they apply to re-
 10 ferrals under subsection (a)(1).

11 **SEC. 115. ACCESS TO OBSTETRICAL AND GYNECOLOGICAL**
 12 **CARE.**

13 (a) IN GENERAL.—If a group health plan, or a health
 14 insurance issuer in connection with the provision of health
 15 insurance coverage, requires or provides for a participant,
 16 beneficiary, or enrollee to designate a participating pri-
 17 mary care health care professional, the plan or issuer—

18 (1) may not require authorization or a referral
 19 by the individual's primary care health care profes-
 20 sional or otherwise for coverage of gynecological care
 21 (including preventive women's health examinations)
 22 and pregnancy-related services provided by a partici-
 23 pating health care professional, including a physi-
 24 cian, who specializes in obstetrics and gynecology to
 25 the extent such care is otherwise covered; and

1 (2) shall treat the ordering of other obstetrical
 2 or gynecological care by such a participating profes-
 3 sional as the authorization of the primary care
 4 health care professional with respect to such care
 5 under the plan or coverage.

6 (b) CONSTRUCTION.—Nothing in subsection (a) shall
 7 be construed to—

8 (1) waive any exclusions of coverage under the
 9 terms of the plan or health insurance coverage with
 10 respect to coverage of obstetrical or gynecological
 11 care; or

12 (2) preclude the group health plan or health in-
 13 surance issuer involved from requiring that the ob-
 14 stetrical or gynecological provider notify the primary
 15 care health care professional or the plan or issuer of
 16 treatment decisions.

17 **SEC. 116. ACCESS TO PEDIATRIC CARE.**

18 (a) PEDIATRIC CARE.—If a group health plan, or a
 19 health insurance issuer in connection with the provision
 20 of health insurance coverage, requires or provides for an
 21 enrollee to designate a participating primary care provider
 22 for a child of such enrollee, the plan or issuer shall permit
 23 the enrollee to designate a physician who specializes in pe-
 24 diatrics as the child's primary care provider.

1 (b) CONSTRUCTION.—Nothing in subsection (a) shall
 2 be construed to waive any exclusions of coverage under
 3 the terms of the plan or health insurance coverage with
 4 respect to coverage of pediatric care.

5 **SEC. 117. CONTINUITY OF CARE.**

6 (a) IN GENERAL.—

7 (1) TERMINATION OF PROVIDER.—If a contract
 8 between a group health plan, or a health insurance
 9 issuer in connection with the provision of health in-
 10 surance coverage, and a health care provider is ter-
 11 minated (as defined in paragraph (3)(B)), or bene-
 12 fits or coverage provided by a health care provider
 13 are terminated because of a change in the terms of
 14 provider participation in a group health plan, and an
 15 individual who is a participant, beneficiary, or en-
 16 rollee in the plan or coverage is undergoing treat-
 17 ment from the provider for an ongoing special condi-
 18 tion (as defined in paragraph (3)(A)) at the time of
 19 such termination, the plan or issuer shall—

20 (A) notify the individual on a timely basis
 21 of such termination and of the right to elect
 22 continuation of coverage of treatment by the
 23 provider under this section; and

24 (B) subject to subsection (c), permit the
 25 individual to elect to continue to be covered

1 with respect to treatment by the provider of
 2 such condition during a transitional period
 3 (provided under subsection (b)).

4 (2) TREATMENT OF TERMINATION OF CON-
 5 TRACT WITH HEALTH INSURANCE ISSUER.—If a
 6 contract for the provision of health insurance cov-
 7 erage between a group health plan and a health in-
 8 surance issuer is terminated and, as a result of such
 9 termination, coverage of services of a health care
 10 provider is terminated with respect to an individual,
 11 the provisions of paragraph (1) (and the succeeding
 12 provisions of this section) shall apply under the plan
 13 in the same manner as if there had been a contract
 14 between the plan and the provider that had been ter-
 15 minated, but only with respect to benefits that are
 16 covered under the plan after the contract termi-
 17 nation.

18 (3) DEFINITIONS.—For purposes of this sec-
 19 tion:

20 (A) ONGOING SPECIAL CONDITION.—The
 21 term “ongoing special condition” has the mean-
 22 ing given such term in section 114(b)(3), and
 23 also includes pregnancy.

24 (B) TERMINATION.—The term “termi-
 25 nated” includes, with respect to a contract, the

1 expiration or nonrenewal of the contract, but
2 does not include a termination of the contract
3 by the plan or issuer for failure to meet applica-
4 ble quality standards or for fraud.

5 (b) TRANSITIONAL PERIOD.—

6 (1) IN GENERAL.—Except as provided in para-
7 graphs (2) through (4), the transitional period under
8 this subsection shall extend up to 90 days (as deter-
9 mined by the treating health care professional) after
10 the date of the notice described in subsection
11 (a)(1)(A) of the provider's termination.

12 (2) SCHEDULED SURGERY AND ORGAN TRANS-
13 PLANTATION.—If surgery or organ transplantation
14 was scheduled for an individual before the date of
15 the announcement of the termination of the provider
16 status under subsection (a)(1)(A) or if the individual
17 on such date was on an established waiting list or
18 otherwise scheduled to have such surgery or trans-
19 plantation, the transitional period under this sub-
20 section with respect to the surgery or transplan-
21 tation shall extend beyond the period under para-
22 graph (1) and until the date of discharge of the indi-
23 vidual after completion of the surgery or transplan-
24 tation.

25 (3) PREGNANCY.—If—

1 (A) a participant, beneficiary, or enrollee
 2 was determined to be pregnant at the time of
 3 a provider's termination of participation; and

4 (B) the provider was treating the preg-
 5 nancy before date of the termination,
 6 the transitional period under this subsection with re-
 7 spect to provider's treatment of the pregnancy shall
 8 extend through the provision of post-partum care di-
 9 rectly related to the delivery.

10 (4) TERMINAL ILLNESS.—If—

11 (A) a participant, beneficiary, or enrollee
 12 was determined to be terminally ill (as deter-
 13 mined under section 1861(dd)(3)(A) of the So-
 14 cial Security Act) at the time of a provider's
 15 termination of participation; and

16 (B) the provider was treating the terminal
 17 illness before the date of termination,
 18 the transitional period under this subsection shall
 19 extend for the remainder of the individual's life for
 20 care directly related to the treatment of the terminal
 21 illness or its medical manifestations.

22 (c) PERMISSIBLE TERMS AND CONDITIONS.—A
 23 group health plan or health insurance issuer may condi-
 24 tion coverage of continued treatment by a provider under
 25 subsection (a)(1)(B) upon the individual notifying the plan

1 of the election of continued coverage and upon the pro-
2 vider agreeing to the following terms and conditions:

3 (1) The provider agrees to accept reimburse-
4 ment from the plan or issuer and individual involved
5 (with respect to cost-sharing) at the rates applicable
6 prior to the start of the transitional period as pay-
7 ment in full (or, in the case described in subsection
8 (a)(2), at the rates applicable under the replacement
9 plan or issuer after the date of the termination of
10 the contract with the health insurance issuer) and
11 not to impose cost-sharing with respect to the indi-
12 vidual in an amount that would exceed the cost-shar-
13 ing that could have been imposed if the contract re-
14 ferred to in subsection (a)(1) had not been termi-
15 nated.

16 (2) The provider agrees to adhere to the quality
17 assurance standards of the plan or issuer responsible
18 for payment under paragraph (1) and to provide to
19 such plan or issuer necessary medical information
20 related to the care provided.

21 (3) The provider agrees otherwise to adhere to
22 such plan's or issuer's policies and procedures, in-
23 cluding procedures regarding referrals and obtaining
24 prior authorization and providing services pursuant

1 to a treatment plan (if any) approved by the plan or
2 issuer.

3 (d) CONSTRUCTION.—Nothing in this section shall be
4 construed to require the coverage of benefits which would
5 not have been covered if the provider involved remained
6 a participating provider.

7 **SEC. 118. ACCESS TO NEEDED PRESCRIPTION DRUGS.**

8 (a) IN GENERAL.—To the extent that a group health
9 plan, or health insurance coverage offered by a health in-
10 surance issuer, provides coverage for benefits with respect
11 to prescription drugs, and limits such coverage to drugs
12 included in a formulary, the plan or issuer shall—

13 (1) ensure the participation of physicians and
14 pharmacists in developing and reviewing such for-
15 mulary;

16 (2) provide for disclosure of the formulary to
17 providers; and

18 (3) in accordance with the applicable quality as-
19 surance and utilization review standards of the plan
20 or issuer, provide for exceptions from the formulary
21 limitation when a non-formulary alternative is medi-
22 cally necessary and appropriate and, in the case of
23 such an exception, apply the same cost-sharing re-
24 quirements that would have applied in the case of a
25 drug covered under the formulary.

1 (b) COVERAGE OF APPROVED DRUGS AND MEDICAL
2 DEVICES.—

3 (1) IN GENERAL.—A group health plan (or
4 health insurance coverage offered in connection with
5 such a plan) that provides any coverage of prescrip-
6 tion drugs or medical devices shall not deny coverage
7 of such a drug or device on the basis that the use
8 is investigational, if the use—

9 (A) in the case of a prescription drug—

10 (i) is included in the labeling author-
11 ized by the application in effect for the
12 drug pursuant to subsection (b) or (j) of
13 section 505 of the Federal Food, Drug,
14 and Cosmetic Act, without regard to any
15 postmarketing requirements that may
16 apply under such Act; or

17 (ii) is included in the labeling author-
18 ized by the application in effect for the
19 drug under section 351 of the Public
20 Health Service Act, without regard to any
21 postmarketing requirements that may
22 apply pursuant to such section; or

23 (B) in the case of a medical device, is in-
24 cluded in the labeling authorized by a regula-
25 tion under subsection (d) or (3) of section 513

1 of the Federal Food, Drug, and Cosmetic Act,
 2 an order under subsection (f) of such section, or
 3 an application approved under section 515 of
 4 such Act, without regard to any postmarketing
 5 requirements that may apply under such Act.

6 (2) CONSTRUCTION.—Nothing in this sub-
 7 section shall be construed as requiring a group
 8 health plan (or health insurance coverage offered in
 9 connection with such a plan) to provide any coverage
 10 of prescription drugs or medical devices.

11 **SEC. 119. COVERAGE FOR INDIVIDUALS PARTICIPATING IN**
 12 **APPROVED CLINICAL TRIALS.**

13 (a) COVERAGE.—

14 (1) IN GENERAL.—If a group health plan, or
 15 health insurance issuer that is providing health in-
 16 surance coverage, provides coverage to a qualified in-
 17 dividual (as defined in subsection (b)), the plan or
 18 issuer—

19 (A) may not deny the individual participa-
 20 tion in the clinical trial referred to in subsection
 21 (b)(2);

22 (B) subject to subsection (c), may not deny
 23 (or limit or impose additional conditions on) the
 24 coverage of routine patient costs for items and

1 services furnished in connection with participa-
2 tion in the trial; and

3 (C) may not discriminate against the indi-
4 vidual on the basis of the enrollee's participa-
5 tion in such trial.

6 (2) EXCLUSION OF CERTAIN COSTS.—For pur-
7 poses of paragraph (1)(B), routine patient costs do
8 not include the cost of the tests or measurements
9 conducted primarily for the purpose of the clinical
10 trial involved.

11 (3) USE OF IN-NETWORK PROVIDERS.—If one
12 or more participating providers is participating in a
13 clinical trial, nothing in paragraph (1) shall be con-
14 strued as preventing a plan or issuer from requiring
15 that a qualified individual participate in the trial
16 through such a participating provider if the provider
17 will accept the individual as a participant in the
18 trial.

19 (b) QUALIFIED INDIVIDUAL DEFINED.—For pur-
20 poses of subsection (a), the term “qualified individual”
21 means an individual who is a participant or beneficiary
22 in a group health plan, or who is an enrollee under health
23 insurance coverage, and who meets the following condi-
24 tions:

1 (1)(A) The individual has a life-threatening or
2 serious illness for which no standard treatment is ef-
3 fective.

4 (B) The individual is eligible to participate in
5 an approved clinical trial according to the trial pro-
6 tocol with respect to treatment of such illness.

7 (C) The individual's participation in the trial
8 offers meaningful potential for significant clinical
9 benefit for the individual.

10 (2) Either—

11 (A) the referring physician is a partici-
12 pating health care professional and has con-
13 cluded that the individual's participation in
14 such trial would be appropriate based upon the
15 individual meeting the conditions described in
16 paragraph (1); or

17 (B) the participant, beneficiary, or enrollee
18 provides medical and scientific information es-
19 tablishing that the individual's participation in
20 such trial would be appropriate based upon the
21 individual meeting the conditions described in
22 paragraph (1).

23 (c) PAYMENT.—

24 (1) IN GENERAL.—Under this section a group
25 health plan or health insurance issuer shall provide

1 for payment for routine patient costs described in
 2 subsection (a)(2) but is not required to pay for costs
 3 of items and services that are reasonably expected
 4 (as determined by the Secretary) to be paid for by
 5 the sponsors of an approved clinical trial.

6 (2) PAYMENT RATE.—In the case of covered
 7 items and services provided by—

8 (A) a participating provider, the payment
 9 rate shall be at the agreed upon rate; or

10 (B) a nonparticipating provider, the pay-
 11 ment rate shall be at the rate the plan or issuer
 12 would normally pay for comparable services
 13 under subparagraph (A).

14 (d) APPROVED CLINICAL TRIAL DEFINED.—

15 (1) IN GENERAL.—In this section, the term
 16 “approved clinical trial” means a clinical research
 17 study or clinical investigation approved and funded
 18 (which may include funding through in-kind con-
 19 tributions) by one or more of the following:

20 (A) The National Institutes of Health.

21 (B) A cooperative group or center of the
 22 National Institutes of Health.

23 (C) Either of the following if the condi-
 24 tions described in paragraph (2) are met:

1 (i) The Department of Veterans Af-
 2 fairs.

3 (ii) The Department of Defense.

4 (2) CONDITIONS FOR DEPARTMENTS.—The
 5 conditions described in this paragraph, for a study
 6 or investigation conducted by a Department, are
 7 that the study or investigation has been reviewed
 8 and approved through a system of peer review that
 9 the Secretary determines—

10 (A) to be comparable to the system of peer
 11 review of studies and investigations used by the
 12 National Institutes of Health; and

13 (B) assures unbiased review of the highest
 14 scientific standards by qualified individuals who
 15 have no interest in the outcome of the review.

16 (e) CONSTRUCTION.—Nothing in this section shall be
 17 construed to limit a plan’s or issuer’s coverage with re-
 18 spect to clinical trials.

19 **Subtitle C—Access to Information**

20 **SEC. 121. PATIENT ACCESS TO INFORMATION.**

21 (a) DISCLOSURE REQUIREMENT.—

22 (1) GROUP HEALTH PLANS.—A group health
 23 plan shall—

24 (A) provide to participants and bene-
 25 ficiaries at the time of initial coverage under

1 the plan (or the effective date of this section, in
2 the case of individuals who are participants or
3 beneficiaries as of such date), and at least an-
4 nually thereafter, the information described in
5 subsection (b) in printed form;

6 (B) provide to participants and bene-
7 ficiaries, within a reasonable period (as speci-
8 fied by the appropriate Secretary) before or
9 after the date of significant changes in the in-
10 formation described in subsection (b), informa-
11 tion in printed form on such significant
12 changes; and

13 (C) upon request, make available to par-
14 ticipants and beneficiaries, the applicable au-
15 thority, and prospective participants and bene-
16 ficiaries, the information described in sub-
17 section (b) or (c) in printed form.

18 (2) HEALTH INSURANCE ISSUERS.—A health
19 insurance issuer in connection with the provision of
20 health insurance coverage shall—

21 (A) provide to individuals enrolled under
22 such coverage at the time of enrollment, and at
23 least annually thereafter, the information de-
24 scribed in subsection (b) in printed form;

1 (B) provide to enrollees, within a reason-
 2 able period (as specified by the appropriate Sec-
 3 retary) before or after the date of significant
 4 changes in the information described in sub-
 5 section (b), information in printed form on such
 6 significant changes; and

7 (C) upon request, make available to the
 8 applicable authority, to individuals who are pro-
 9 spective enrollees, and to the public the infor-
 10 mation described in subsection (b) or (c) in
 11 printed form.

12 (b) INFORMATION PROVIDED.—The information de-
 13 scribed in this subsection with respect to a group health
 14 plan or health insurance coverage offered by a health in-
 15 surance issuer includes the following:

16 (1) SERVICE AREA.—The service area of the
 17 plan or issuer.

18 (2) BENEFITS.—Benefits offered under the
 19 plan or coverage, including—

20 (A) covered benefits, including benefit lim-
 21 its and coverage exclusions;

22 (B) cost sharing, such as deductibles, coin-
 23 surance, and copayment amounts, including any
 24 liability for balance billing, any maximum limi-
 25 tations on out of pocket expenses, and the max-

imum out of pocket costs for services that are provided by nonparticipating providers or that are furnished without meeting the applicable utilization review requirements;

(C) the extent to which benefits may be obtained from nonparticipating providers;

(D) the extent to which a participant, beneficiary, or enrollee may select from among participating providers and the types of providers participating in the plan or issuer network;

(E) process for determining experimental coverage; and

(F) use of a prescription drug formulary.

(3) ACCESS.—A description of the following:

(A) The number, mix, and distribution of providers under the plan or coverage.

(B) Out-of-network coverage (if any) provided by the plan or coverage.

(C) Any point-of-service option (including any supplemental premium or cost-sharing for such option).

(D) The procedures for participants, beneficiaries, and enrollees to select, access, and change participating primary and specialty providers.

1 (E) The rights and procedures for obtain-
 2 ing referrals (including standing referrals) to
 3 participating and nonparticipating providers.

4 (F) The name, address, and telephone
 5 number of participating health care providers
 6 and an indication of whether each such provider
 7 is available to accept new patients.

8 (G) Any limitations imposed on the selec-
 9 tion of qualifying participating health care pro-
 10 viders, including any limitations imposed under
 11 section 112(b)(2).

12 (H) How the plan or issuer addresses the
 13 needs of participants, beneficiaries, and enroll-
 14 ees and others who do not speak English or
 15 who have other special communications needs in
 16 accessing providers under the plan or coverage,
 17 including the provision of information described
 18 in this subsection and subsection (c) to such in-
 19 dividuals.

20 (4) OUT-OF-AREA COVERAGE.—Out-of-area cov-
 21 erage provided by the plan or issuer.

22 (5) EMERGENCY COVERAGE.—Coverage of
 23 emergency services, including—

24 (A) the appropriate use of emergency serv-
 25 ices, including use of the 911 telephone system

1 or its local equivalent in emergency situations
 2 and an explanation of what constitutes an
 3 emergency situation;

4 (B) the process and procedures of the plan
 5 or issuer for obtaining emergency services; and

6 (C) the locations of (i) emergency depart-
 7 ments, and (ii) other settings, in which plan
 8 physicians and hospitals provide emergency
 9 services and post-stabilization care.

10 (6) PERCENTAGE OF PREMIUMS USED FOR
 11 BENEFITS (LOSS-RATIOS).—In the case of health in-
 12 surance coverage only (and not with respect to group
 13 health plans that do not provide coverage through
 14 health insurance coverage), a description of the over-
 15 all loss-ratio for the coverage (as defined in accord-
 16 ance with rules established or recognized by the Sec-
 17 retary of Health and Human Services).

18 (7) PRIOR AUTHORIZATION RULES.—Rules re-
 19 garding prior authorization or other review require-
 20 ments that could result in noncoverage or non-
 21 payment.

22 (8) GRIEVANCE AND APPEALS PROCEDURES.—
 23 All appeal or grievance rights and procedures under
 24 the plan or coverage, including the method for filing
 25 grievances and the time frames and circumstances

1 for acting on grievances and appeals, who is the ap-
2 plicable authority with respect to the plan or issuer.

3 (9) QUALITY ASSURANCE.—Any information
4 made public by an accrediting organization in the
5 process of accreditation of the plan or issuer or any
6 additional quality indicators the plan or issuer
7 makes available.

8 (10) INFORMATION ON ISSUER.—Notice of ap-
9 propriate mailing addresses and telephone numbers
10 to be used by participants, beneficiaries, and enroll-
11 ees in seeking information or authorization for treat-
12 ment.

13 (11) NOTICE OF REQUIREMENTS.—Notice of
14 the requirements of this title.

15 (12) AVAILABILITY OF INFORMATION ON RE-
16 QUEST.—Notice that the information described in
17 subsection (c) is available upon request.

18 (c) INFORMATION MADE AVAILABLE UPON RE-
19 QUEST.—The information described in this subsection is
20 the following:

21 (1) UTILIZATION REVIEW ACTIVITIES.—A de-
22 scription of procedures used and requirements (in-
23 cluding circumstances, time frames, and appeal
24 rights) under any utilization review program under

1 section 101, including under any drug formulary
2 program under section 118.

3 (2) GRIEVANCE AND APPEALS INFORMATION.—
4 Information on the number of grievances and ap-
5 peals and on the disposition in the aggregate of such
6 matters.

7 (3) METHOD OF PHYSICIAN COMPENSATION.—
8 A general description by category (including salary,
9 fee-for-service, capitation, and such other categories
10 as may be specified in regulations of the Secretary)
11 of the applicable method by which a specified pro-
12 spective or treating health care professional is (or
13 would be) compensated in connection with the provi-
14 sion of health care under the plan or coverage.

15 (4) SPECIFIC INFORMATION ON CREDENTIALS
16 OF PARTICIPATING PROVIDERS.—In the case of each
17 participating provider, a description of the creden-
18 tials of the provider.

19 (5) FORMULARY RESTRICTIONS.—A description
20 of the nature of any drug formula restrictions.

21 (6) PARTICIPATING PROVIDER LIST.—A list of
22 current participating health care providers.

23 (d) CONSTRUCTION.—Nothing in this section shall be
24 construed as requiring public disclosure of individual con-

1 tracts or financial arrangements between a group health
 2 plan or health insurance issuer and any provider.

3 **Subtitle D—Protecting the Doctor-** 4 **Patient Relationship**

5 **SEC. 131. PROHIBITION OF INTERFERENCE WITH CERTAIN** 6 **MEDICAL COMMUNICATIONS.**

7 (a) GENERAL RULE.—The provisions of any contract
 8 or agreement, or the operation of any contract or agree-
 9 ment, between a group health plan or health insurance
 10 issuer in relation to health insurance coverage (including
 11 any partnership, association, or other organization that
 12 enters into or administers such a contract or agreement)
 13 and a health care provider (or group of health care pro-
 14 viders) shall not prohibit or otherwise restrict a health
 15 care professional from advising such a participant, bene-
 16 ficiary, or enrollee who is a patient of the professional
 17 about the health status of the individual or medical care
 18 or treatment for the individual’s condition or disease, re-
 19 gardless of whether benefits for such care or treatment
 20 are provided under the plan or coverage, if the professional
 21 is acting within the lawful scope of practice.

22 (b) NULLIFICATION.—Any contract provision or
 23 agreement that restricts or prohibits medical communica-
 24 tions in violation of subsection (a) shall be null and void.

1 **SEC. 132. PROHIBITION OF DISCRIMINATION AGAINST PRO-**
2 **VIDERS BASED ON LICENSURE.**

3 (a) IN GENERAL.—A group health plan and a health
4 insurance issuer offering health insurance coverage shall
5 not discriminate with respect to participation or indem-
6 nification as to any provider who is acting within the scope
7 of the provider's license or certification under applicable
8 State law, solely on the basis of such license or certifi-
9 cation.

10 (b) CONSTRUCTION.—Subsection (a) shall not be
11 construed—

12 (1) as requiring the coverage under a group
13 health plan or health insurance coverage of par-
14 ticular benefits or services or to prohibit a plan or
15 issuer from including providers only to the extent
16 necessary to meet the needs of the plan's or issuer's
17 participants, beneficiaries, or enrollees or from es-
18 tablishing any measure designed to maintain quality
19 and control costs consistent with the responsibilities
20 of the plan or issuer;

21 (2) to override any State licensure or scope-of-
22 practice law; or

23 (3) as requiring a plan or issuer that offers net-
24 work coverage to include for participation every will-
25 ing provider who meets the terms and conditions of
26 the plan or issuer.

1 **SEC. 133. PROHIBITION AGAINST IMPROPER INCENTIVE**
2 **ARRANGEMENTS.**

3 (a) IN GENERAL.—A group health plan and a health
4 insurance issuer offering health insurance coverage may
5 not operate any physician incentive plan (as defined in
6 subparagraph (B) of section 1876(i)(8) of the Social Secu-
7 rity Act) unless the requirements described in clauses (i),
8 (ii)(I), and (iii) of subparagraph (A) of such section are
9 met with respect to such a plan.

10 (b) APPLICATION.—For purposes of carrying out
11 paragraph (1), any reference in section 1876(i)(8) of the
12 Social Security Act to the Secretary, an eligible organiza-
13 tion, or an individual enrolled with the organization shall
14 be treated as a reference to the applicable authority, a
15 group health plan or health insurance issuer, respectively,
16 and a participant, beneficiary, or enrollee with the plan
17 or organization, respectively.

18 (c) CONSTRUCTION.—Nothing in this section shall be
19 construed as prohibiting all capitation and similar ar-
20 rangements or all provider discount arrangements.

21 **SEC. 134. PAYMENT OF CLAIMS.**

22 A group health plan, and a health insurance issuer
23 offering group health insurance coverage, shall provide for
24 prompt payment of claims submitted for health care serv-
25 ices or supplies furnished to a participant, beneficiary, or
26 enrollee with respect to benefits covered by the plan or

1 issuer, in a manner consistent with the provisions of sec-
 2 tions 1816(c)(2) and 1842(c)(2) of the Social Security Act
 3 (42 U.S.C. 1395h(c)(2) and 42 U.S.C. 1395u(c)(2)), ex-
 4 cept that for purposes of this section, subparagraph (C)
 5 of section 1816(c)(2) of the Social Security Act shall be
 6 treated as applying to claims received from a participant,
 7 beneficiary, or enrollee as well as claims referred to in
 8 such subparagraph.

9 **SEC. 135. PROTECTION FOR PATIENT ADVOCACY.**

10 (a) PROTECTION FOR USE OF UTILIZATION REVIEW
 11 AND GRIEVANCE PROCESS.—A group health plan, and a
 12 health insurance issuer with respect to the provision of
 13 health insurance coverage, may not retaliate against a par-
 14 ticipant, beneficiary, enrollee, or health care provider
 15 based on the participant's, beneficiary's, enrollee's or pro-
 16 vider's use of, or participation in, a utilization review proc-
 17 ess or a grievance process of the plan or issuer (including
 18 an internal or external review or appeal process) under
 19 this title.

20 (b) PROTECTION FOR QUALITY ADVOCACY BY
 21 HEALTH CARE PROFESSIONALS.—

22 (1) IN GENERAL.—A group health plan or
 23 health insurance issuer may not retaliate or dis-
 24 criminate against a protected health care profes-
 25 sional because the professional in good faith—

1 (A) discloses information relating to the
2 care, services, or conditions affecting one or
3 more participants, beneficiaries, or enrollees of
4 the plan or issuer to an appropriate public reg-
5 ulatory agency, an appropriate private accredi-
6 tation body, or appropriate management per-
7 sonnel of the plan or issuer; or

8 (B) initiates, cooperates, or otherwise par-
9 ticipates in an investigation or proceeding by
10 such an agency with respect to such care, serv-
11 ices, or conditions.

12 If an institutional health care provider is a partici-
13 pating provider with such a plan or issuer or other-
14 wise receives payments for benefits provided by such
15 a plan or issuer, the provisions of the previous sen-
16 tence shall apply to the provider in relation to care,
17 services, or conditions affecting one or more patients
18 within an institutional health care provider in the
19 same manner as they apply to the plan or issuer in
20 relation to care, services, or conditions provided to
21 one or more participants, beneficiaries, or enrollees;
22 and for purposes of applying this sentence, any ref-
23 erence to a plan or issuer is deemed a reference to
24 the institutional health care provider.

1 (2) GOOD FAITH ACTION.—For purposes of
2 paragraph (1), a protected health care professional
3 is considered to be acting in good faith with respect
4 to disclosure of information or participation if, with
5 respect to the information disclosed as part of the
6 action—

7 (A) the disclosure is made on the basis of
8 personal knowledge and is consistent with that
9 degree of learning and skill ordinarily possessed
10 by health care professionals with the same li-
11 censure or certification and the same experi-
12 ence;

13 (B) the professional reasonably believes the
14 information to be true;

15 (C) the information evidences either a vio-
16 lation of a law, rule, or regulation, of an appli-
17 cable accreditation standard, or of a generally
18 recognized professional or clinical standard or
19 that a patient is in imminent hazard of loss of
20 life or serious injury; and

21 (D) subject to subparagraphs (B) and (C)
22 of paragraph (3), the professional has followed
23 reasonable internal procedures of the plan,
24 issuer, or institutional health care provider es-

1 tablished for the purpose of addressing quality
2 concerns before making the disclosure.

3 (3) EXCEPTION AND SPECIAL RULE.—

4 (A) GENERAL EXCEPTION.—Paragraph (1)
5 does not protect disclosures that would violate
6 Federal or State law or diminish or impair the
7 rights of any person to the continued protection
8 of confidentiality of communications provided
9 by such law.

10 (B) NOTICE OF INTERNAL PROCEDURES.—
11 Subparagraph (D) of paragraph (2) shall not
12 apply unless the internal procedures involved
13 are reasonably expected to be known to the
14 health care professional involved. For purposes
15 of this subparagraph, a health care professional
16 is reasonably expected to know of internal pro-
17 cedures if those procedures have been made
18 available to the professional through distribu-
19 tion or posting.

20 (C) INTERNAL PROCEDURE EXCEPTION.—
21 Subparagraph (D) of paragraph (2) also shall
22 not apply if—

- 23 (i) the disclosure relates to an immi-
24 nent hazard of loss of life or serious injury
25 to a patient;

1 (ii) the disclosure is made to an ap-
2 propriate private accreditation body pursu-
3 ant to disclosure procedures established by
4 the body; or

5 (iii) the disclosure is in response to an
6 inquiry made in an investigation or pro-
7 ceeding of an appropriate public regulatory
8 agency and the information disclosed is
9 limited to the scope of the investigation or
10 proceeding.

11 (4) ADDITIONAL CONSIDERATIONS.—It shall
12 not be a violation of paragraph (1) to take an ad-
13 verse action against a protected health care profes-
14 sional if the plan, issuer, or provider taking the ad-
15 verse action involved demonstrates that it would
16 have taken the same adverse action even in the ab-
17 sence of the activities protected under such para-
18 graph.

19 (5) NOTICE.—A group health plan, health in-
20 surance issuer, and institutional health care provider
21 shall post a notice, to be provided or approved by
22 the Secretary of Labor, setting forth excerpts from,
23 or summaries of, the pertinent provisions of this
24 subsection and information pertaining to enforce-
25 ment of such provisions.

1 (6) CONSTRUCTIONS.—

2 (A) DETERMINATIONS OF COVERAGE.—

3 Nothing in this subsection shall be construed to
 4 prohibit a plan or issuer from making a deter-
 5 mination not to pay for a particular medical
 6 treatment or service or the services of a type of
 7 health care professional.

8 (B) ENFORCEMENT OF PEER REVIEW PRO-
 9 TOCOLS AND INTERNAL PROCEDURES.—Noth-
 10 ing in this subsection shall be construed to pro-
 11 hibit a plan, issuer, or provider from estab-
 12 lishing and enforcing reasonable peer review or
 13 utilization review protocols or determining
 14 whether a protected health care professional has
 15 complied with those protocols or from estab-
 16 lishing and enforcing internal procedures for
 17 the purpose of addressing quality concerns.

18 (C) RELATION TO OTHER RIGHTS.—Noth-
 19 ing in this subsection shall be construed to
 20 abridge rights of participants, beneficiaries, en-
 21 rollees, and protected health care professionals
 22 under other applicable Federal or State laws.

23 (7) PROTECTED HEALTH CARE PROFESSIONAL
 24 DEFINED.—For purposes of this subsection, the
 25 term “protected health care professional” means an

1 individual who is a licensed or certified health care
 2 professional and who—

3 (A) with respect to a group health plan or
 4 health insurance issuer, is an employee of the
 5 plan or issuer or has a contract with the plan
 6 or issuer for provision of services for which ben-
 7 efits are available under the plan or issuer; or

8 (B) with respect to an institutional health
 9 care provider, is an employee of the provider or
 10 has a contract or other arrangement with the
 11 provider respecting the provision of health care
 12 services.

13 **Subtitle E—Definitions**

14 **SEC. 151. DEFINITIONS.**

15 (a) INCORPORATION OF GENERAL DEFINITIONS.—
 16 Except as otherwise provided, the provisions of section
 17 2791 of the Public Health Service Act shall apply for pur-
 18 poses of this title in the same manner as they apply for
 19 purposes of title XXVII of such Act.

20 (b) SECRETARY.—Except as otherwise provided, the
 21 term “Secretary” means the Secretary of Health and
 22 Human Services, in consultation with the Secretary of
 23 Labor and the term “appropriate Secretary” means the
 24 Secretary of Health and Human Services in relation to
 25 carrying out this title under sections 2706 and 2751 of

1 the Public Health Service Act and the Secretary of Labor
 2 in relation to carrying out this title under section 713 of
 3 the Employee Retirement Income Security Act of 1974.

4 (c) ADDITIONAL DEFINITIONS.—For purposes of this
 5 title:

6 (1) ACTIVELY PRACTICING.—The term “actively
 7 practicing” means, with respect to a physician or
 8 other health care professional, such a physician or
 9 professional who provides professional services to in-
 10 dividual patients on average at least two full days
 11 per week.

12 (2) APPLICABLE AUTHORITY.—The term “ap-
 13 plicable authority” means—

14 (A) in the case of a group health plan, the
 15 Secretary of Health and Human Services and
 16 the Secretary of Labor; and

17 (B) in the case of a health insurance issuer
 18 with respect to a specific provision of this title,
 19 the applicable State authority (as defined in
 20 section 2791(d) of the Public Health Service
 21 Act), or the Secretary of Health and Human
 22 Services, if such Secretary is enforcing such
 23 provision under section 2722(a)(2) or
 24 2761(a)(2) of the Public Health Service Act.

1 (3) CLINICAL PEER.—The term “clinical peer”
2 means, with respect to a review or appeal, an ac-
3 tively practicing physician (allopathic or osteopathic)
4 or other actively practicing health care professional
5 who holds a nonrestricted license, and who is appro-
6 priately credentialed in the same or similar specialty
7 or subspecialty (as appropriate) as typically handles
8 the medical condition, procedure, or treatment under
9 review or appeal and includes a pediatric specialist
10 where appropriate; except that only a physician
11 (allopathic or osteopathic) may be a clinical peer
12 with respect to the review or appeal of treatment
13 recommended or rendered by a physician.

14 (4) ENROLLEE.—The term “enrollee” means,
15 with respect to health insurance coverage offered by
16 a health insurance issuer, an individual enrolled with
17 the issuer to receive such coverage.

18 (5) GROUP HEALTH PLAN.—The term “group
19 health plan” has the meaning given such term in
20 section 733(a) of the Employee Retirement Income
21 Security Act of 1974 and in section 2791(a)(1) of
22 the Public Health Service Act.

23 (6) HEALTH CARE PROFESSIONAL.—The term
24 “health care professional” means an individual who
25 is licensed, accredited, or certified under State law

1 to provide specified health care services and who is
2 operating within the scope of such licensure, accredi-
3 tation, or certification.

4 (7) HEALTH CARE PROVIDER.—The term
5 “health care provider” includes a physician or other
6 health care professional, as well as an institutional
7 or other facility or agency that provides health care
8 services and that is licensed, accredited, or certified
9 to provide health care items and services under ap-
10 plicable State law.

11 (8) NETWORK.—The term “network” means,
12 with respect to a group health plan or health insur-
13 ance issuer offering health insurance coverage, the
14 participating health care professionals and providers
15 through whom the plan or issuer provides health
16 care items and services to participants, beneficiaries,
17 or enrollees.

18 (9) NONPARTICIPATING.—The term “non-
19 participating” means, with respect to a health care
20 provider that provides health care items and services
21 to a participant, beneficiary, or enrollee under group
22 health plan or health insurance coverage, a health
23 care provider that is not a participating health care
24 provider with respect to such items and services.

1 (10) PARTICIPATING.—The term “partici-
 2 pating” means, with respect to a health care pro-
 3 vider that provides health care items and services to
 4 a participant, beneficiary, or enrollee under group
 5 health plan or health insurance coverage offered by
 6 a health insurance issuer, a health care provider that
 7 furnishes such items and services under a contract
 8 or other arrangement with the plan or issuer.

9 (11) PRIOR AUTHORIZATION.—The term “prior
 10 authorization” means the process of obtaining prior
 11 approval from a health insurance issuer or group
 12 health plan for the provision or coverage of medical
 13 services.

14 **SEC. 152. PREEMPTION; STATE FLEXIBILITY; CONSTRUC-**
 15 **TION.**

16 (a) CONTINUED APPLICABILITY OF STATE LAW
 17 WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

18 (1) IN GENERAL.—Subject to paragraph (2),
 19 this title shall not be construed to supersede any
 20 provision of State law which establishes, implements,
 21 or continues in effect any standard or requirement
 22 solely relating to health insurance issuers (in connec-
 23 tion with group health insurance coverage or other-
 24 wise) except to the extent that such standard or re-

1 requirement prevents the application of a requirement
2 of this title.

3 (2) CONTINUED PREEMPTION WITH RESPECT
4 TO GROUP HEALTH PLANS.—Nothing in this title
5 shall be construed to affect or modify the provisions
6 of section 514 of the Employee Retirement Income
7 Security Act of 1974 with respect to group health
8 plans.

9 (b) DEFINITIONS.—For purposes of this section:

10 (1) STATE LAW.—The term “State law” in-
11 cludes all laws, decisions, rules, regulations, or other
12 State action having the effect of law, of any State.
13 A law of the United States applicable only to the
14 District of Columbia shall be treated as a State law
15 rather than a law of the United States.

16 (2) STATE.—The term “State” includes a
17 State, the District of Columbia, Puerto Rico, the
18 Virgin Islands, Guam, American Samoa, the North-
19 ern Mariana Islands, any political subdivisions of
20 such, or any agency or instrumentality of such.

21 **SEC. 153. EXCLUSIONS.**

22 (a) NO BENEFIT REQUIREMENTS.—Nothing in this
23 title shall be construed to require a group health plan or
24 a health insurance issuer offering health insurance cov-
25 erage to include specific items and services under the

1 terms of such a plan or coverage, other than those that
 2 are provided for under the terms of such plan or coverage.

3 (b) EXCLUSION FROM ACCESS TO CARE MANAGED
 4 CARE PROVISIONS FOR FEE-FOR-SERVICE COVERAGE.—

5 (1) IN GENERAL.—The provisions of sections
 6 111 through 117 shall not apply to a group health
 7 plan or health insurance coverage if the only cov-
 8 erage offered under the plan or coverage is fee-for-
 9 service coverage (as defined in paragraph (2)).

10 (2) FEE-FOR-SERVICE COVERAGE DEFINED.—
 11 For purposes of this subsection, the term “fee-for-
 12 service coverage” means coverage under a group
 13 health plan or health insurance coverage that—

14 (A) reimburses hospitals, health profes-
 15 sionals, and other providers on the basis of a
 16 rate determined by the plan or issuer on a fee-
 17 for-service basis without placing the provider at
 18 financial risk;

19 (B) does not vary reimbursement for such
 20 a provider based on an agreement to contract
 21 terms and conditions or the utilization of health
 22 care items or services relating to such provider;

23 (C) does not restrict the selection of pro-
 24 viders among those who are lawfully authorized
 25 to provide the covered services and agree to ac-

1 cept the terms and conditions of payment estab-
2 lished under the plan or by the issuer; and

3 (D) for which the plan or issuer does not
4 require prior authorization before providing cov-
5 erage for any services.

6 **SEC. 154. COVERAGE OF LIMITED SCOPE PLANS.**

7 Only for purposes of applying the requirements of
8 this title under sections 2707 and 2753 of the Public
9 Health Service Act and section 714 of the Employee Re-
10 tirement Income Security Act of 1974, section
11 2791(c)(2)(A), and section 733(c)(2)(A) of the Employee
12 Retirement Income Security Act of 1974 shall be deemed
13 not to apply.

14 **SEC. 155. REGULATIONS.**

15 The Secretaries of Health and Human Services and
16 Labor shall issue such regulations as may be necessary
17 or appropriate to carry out this title. Such regulations
18 shall be issued consistent with section 104 of Health In-
19 surance Portability and Accountability Act of 1996. Such
20 Secretaries may promulgate any interim final rules as the
21 Secretaries determine are appropriate to carry out this
22 title.

1 **TITLE II—APPLICATION OF**
 2 **QUALITY CARE STANDARDS**
 3 **TO GROUP HEALTH PLANS**
 4 **AND HEALTH INSURANCE**
 5 **COVERAGE UNDER THE PUB-**
 6 **LIC HEALTH SERVICE ACT**

7 **SEC. 201. APPLICATION TO GROUP HEALTH PLANS AND**
 8 **GROUP HEALTH INSURANCE COVERAGE.**

9 (a) IN GENERAL.—Subpart 2 of part A of title
 10 XXVII of the Public Health Service Act is amended by
 11 adding at the end the following new section:

12 **“SEC. 2707. PATIENT PROTECTION STANDARDS.**

13 “(a) IN GENERAL.—Each group health plan shall
 14 comply with patient protection requirements under title I
 15 of the Patients’ Bill of Rights Act, and each health insur-
 16 ance issuer shall comply with patient protection require-
 17 ments under such title with respect to group health insur-
 18 ance coverage it offers, and such requirements shall be
 19 deemed to be incorporated into this subsection.

20 “(b) NOTICE.—A group health plan shall comply with
 21 the notice requirement under section 711(d) of the Em-
 22 ployee Retirement Income Security Act of 1974 with re-
 23 spect to the requirements referred to in subsection (a) and
 24 a health insurance issuer shall comply with such notice

1 requirement as if such section applied to such issuer and
 2 such issuer were a group health plan.”.

3 (b) CONFORMING AMENDMENT.—Section
 4 2721(b)(2)(A) of such Act (42 U.S.C. 300gg–21(b)(2)(A))
 5 is amended by inserting “(other than section 2707)” after
 6 “requirements of such subparts”.

7 **SEC. 202. APPLICATION TO INDIVIDUAL HEALTH INSUR-**
 8 **ANCE COVERAGE.**

9 Part B of title XXVII of the Public Health Service
 10 Act is amended by inserting after section 2752 the fol-
 11 lowing new section:

12 **“SEC. 2753. PATIENT PROTECTION STANDARDS.**

13 “(a) IN GENERAL.—Each health insurance issuer
 14 shall comply with patient protection requirements under
 15 title I of the Patients’ Bill of Rights Act with respect to
 16 individual health insurance coverage it offers, and such re-
 17 quirements shall be deemed to be incorporated into this
 18 subsection.

19 “(b) NOTICE.—A health insurance issuer under this
 20 part shall comply with the notice requirement under sec-
 21 tion 711(d) of the Employee Retirement Income Security
 22 Act of 1974 with respect to the requirements of such title
 23 as if such section applied to such issuer and such issuer
 24 were a group health plan.”.

1 **TITLE III—AMENDMENTS TO**
 2 **THE EMPLOYEE RETIREMENT**
 3 **INCOME SECURITY ACT OF**
 4 **1974**

5 **SEC. 301. APPLICATION OF PATIENT PROTECTION STAND-**
 6 **ARDS TO GROUP HEALTH PLANS AND GROUP**
 7 **HEALTH INSURANCE COVERAGE UNDER THE**
 8 **EMPLOYEE RETIREMENT INCOME SECURITY**
 9 **ACT OF 1974.**

10 Subpart B of part 7 of subtitle B of title I of the
 11 Employee Retirement Income Security Act of 1974 is
 12 amended by adding at the end the following new section:

13 **“SEC. 714. PATIENT PROTECTION STANDARDS.**

14 “(a) IN GENERAL.—Subject to subsection (b), a
 15 group health plan (and a health insurance issuer offering
 16 group health insurance coverage in connection with such
 17 a plan) shall comply with the requirements of title I of
 18 the Patients’ Bill of Rights Act (as in effect as of the date
 19 of the enactment of such Act), and such requirements
 20 shall be deemed to be incorporated into this subsection.

21 “(b) PLAN SATISFACTION OF CERTAIN REQUIRE-
 22 MENTS.—

23 “(1) SATISFACTION OF CERTAIN REQUIRE-
 24 MENTS THROUGH INSURANCE.—For purposes of
 25 subsection (a), insofar as a group health plan pro-

1 vides benefits in the form of health insurance cov-
2 erage through a health insurance issuer, the plan
3 shall be treated as meeting the following require-
4 ments of title I of the Patients' Bill of Rights Act
5 with respect to such benefits and not be considered
6 as failing to meet such requirements because of a
7 failure of the issuer to meet such requirements so
8 long as the plan sponsor or its representatives did
9 not cause such failure by the issuer:

10 “(A) Section 112 (relating to choice of pro-
11 viders).

12 “(B) Section 113 (relating to access to
13 emergency care).

14 “(C) Section 114 (relating to access to
15 specialty care).

16 “(D) Section 115 (relating to access to ob-
17 stetrical and gynecological care).

18 “(E) Section 116 (relating to access to pe-
19 diatric care).

20 “(F) Section 117(a)(1) (relating to con-
21 tinuity in case of termination of provider con-
22 tract) and section 117(a)(2) (relating to con-
23 tinuity in case of termination of issuer con-
24 tract), but only insofar as a replacement issuer
25 assumes the obligation for continuity of care.

1 “(G) Section 118 (relating to access to
2 needed prescription drugs).

3 “(H) Section 119 (relating to coverage for
4 individuals participating in approved clinical
5 trials.)

6 “(I) Section 134 (relating to payment of
7 claims).

8 “(2) INFORMATION.—With respect to informa-
9 tion required to be provided or made available under
10 section 121, in the case of a group health plan that
11 provides benefits in the form of health insurance
12 coverage through a health insurance issuer, the Sec-
13 retary shall determine the circumstances under
14 which the plan is not required to provide or make
15 available the information (and is not liable for the
16 issuer’s failure to provide or make available the in-
17 formation), if the issuer is obligated to provide and
18 make available (or provides and makes available)
19 such information.

20 “(3) GRIEVANCE AND INTERNAL APPEALS.—
21 With respect to the internal appeals process and the
22 grievance system required to be established under
23 sections 102 and 104, in the case of a group health
24 plan that provides benefits in the form of health in-
25 surance coverage through a health insurance issuer,

1 the Secretary shall determine the circumstances
2 under which the plan is not required to provide for
3 such process and system (and is not liable for the
4 issuer's failure to provide for such process and sys-
5 tem), if the issuer is obligated to provide for (and
6 provides for) such process and system.

7 “(4) EXTERNAL APPEALS.—Pursuant to rules
8 of the Secretary, insofar as a group health plan en-
9 ters into a contract with a qualified external appeal
10 entity for the conduct of external appeal activities in
11 accordance with section 103, the plan shall be treat-
12 ed as meeting the requirement of such section and
13 is not liable for the entity's failure to meet any re-
14 quirements under such section.

15 “(5) APPLICATION TO PROHIBITIONS.—Pursu-
16 ant to rules of the Secretary, if a health insurance
17 issuer offers health insurance coverage in connection
18 with a group health plan and takes an action in vio-
19 lation of any of the following sections, the group
20 health plan shall not be liable for such violation un-
21 less the plan caused such violation:

22 “(A) Section 131 (relating to prohibition of
23 interference with certain medical communica-
24 tions).

1 “(B) Section 132 (relating to prohibition
2 of discrimination against providers based on li-
3 censure).

4 “(C) Section 133 (relating to prohibition
5 against improper incentive arrangements).

6 “(D) Section 135 (relating to protection
7 for patient advocacy).

8 “(6) CONSTRUCTION.—Nothing in this sub-
9 section shall be construed to affect or modify the re-
10 sponsibilities of the fiduciaries of a group health
11 plan under part 4 of subtitle B.

12 “(7) APPLICATION TO CERTAIN PROHIBITIONS
13 AGAINST RETALIATION.—With respect to compliance
14 with the requirements of section 135(b)(1) of the
15 Patients’ Bill of Rights Act, for purposes of this
16 subtitle the term ‘group health plan’ is deemed to in-
17 clude a reference to an institutional health care pro-
18 vider.

19 “(c) ENFORCEMENT OF CERTAIN REQUIREMENTS.—

20 “(1) COMPLAINTS.—Any protected health care
21 professional who believes that the professional has
22 been retaliated or discriminated against in violation
23 of section 135(b)(1) of the Patients’ Bill of Rights
24 Act may file with the Secretary a complaint within

1 180 days of the date of the alleged retaliation or dis-
2 crimination.

3 “(2) INVESTIGATION.—The Secretary shall in-
4 vestigate such complaints and shall determine if a
5 violation of such section has occurred and, if so,
6 shall issue an order to ensure that the protected
7 health care professional does not suffer any loss of
8 position, pay, or benefits in relation to the plan,
9 issuer, or provider involved, as a result of the viola-
10 tion found by the Secretary.

11 “(d) CONFORMING REGULATIONS.—The Secretary
12 may issue regulations to coordinate the requirements on
13 group health plans under this section with the require-
14 ments imposed under the other provisions of this title.”.

15 (b) SATISFACTION OF ERISA CLAIMS PROCEDURE
16 REQUIREMENT.—Section 503 of such Act (29 U.S.C.
17 1133) is amended by inserting “(a)” after “SEC. 503.”
18 and by adding at the end the following new subsection:

19 “(b) In the case of a group health plan (as defined
20 in section 733) compliance with the requirements of sub-
21 title A of title I of the Patients Bill of Rights Act in the
22 case of a claims denial shall be deemed compliance with
23 subsection (a) with respect to such claims denial.”.

1 (c) CONFORMING AMENDMENTS.—(1) Section 732(a)
 2 of such Act (29 U.S.C. 1185(a)) is amended by striking
 3 “section 711” and inserting “sections 711 and 714”.

4 (2) The table of contents in section 1 of such Act
 5 is amended by inserting after the item relating to section
 6 713 the following new item:

“Sec. 714. Patient protection standards.”.

7 (3) Section 502(b)(3) of such Act (29 U.S.C.
 8 1132(b)(3)) is amended by inserting “(other than section
 9 135(b))” after “part 7”.

10 **SEC. 302. ERISA PREEMPTION NOT TO APPLY TO CERTAIN**
 11 **ACTIONS INVOLVING HEALTH INSURANCE**
 12 **POLICYHOLDERS.**

13 (a) IN GENERAL.—Section 514 of the Employee Re-
 14 tirement Income Security Act of 1974 (29 U.S.C. 1144)
 15 (as amended by section 301(b)) is amended further by
 16 adding at the end the following subsections:

17 “(f) PREEMPTION NOT TO APPLY TO CERTAIN AC-
 18 TIONS ARISING OUT OF PROVISION OF HEALTH BENE-
 19 FITS.—

20 “(1) NON-PREEMPTION OF CERTAIN CAUSES OF
 21 ACTION.—

22 “(A) IN GENERAL.—Except as provided in
 23 this subsection, nothing in this title shall be
 24 construed to invalidate, impair, or supersede
 25 any cause of action by a participant or bene-

1 ficiary (or the estate of a participant or bene-
 2 ficiary) under State law to recover damages re-
 3 sulting from personal injury or for wrongful
 4 death against any person—

5 “(i) in connection with the provision
 6 of insurance, administrative services, or
 7 medical services by such person to or for
 8 a group health plan as defined in section
 9 733), or

10 “(ii) that arises out of the arrange-
 11 ment by such person for the provision of
 12 such insurance, administrative services, or
 13 medical services by other persons.

14 “(B) LIMITATION ON PUNITIVE DAM-
 15 AGES.—

16 “(i) IN GENERAL.—No person shall be
 17 liable for any punitive, exemplary, or simi-
 18 lar damages in the case of a cause of ac-
 19 tion brought under subparagraph (A) if—

20 “(I) it relates to an externally
 21 appealable decision (as defined in sub-
 22 section (a)(2) of section 103 of the
 23 Patients’ Bill of Rights Act);

1 “(II) an external appeal with re-
2 spect to such decision was completed
3 under such section 103;

4 “(III) in the case such external
5 appeal was initiated by the plan or
6 issuer filing the request for the exter-
7 nal appeal, the request was filed on a
8 timely basis before the date the action
9 was brought or, if later, within 30
10 days after the date the externally ap-
11 pealable decision was made; and

12 “(IV) the plan or issuer complied
13 with the determination of the external
14 appeal entity upon receipt of the de-
15 termination of the external appeal en-
16 tity.

17 The provisions of this clause supersede any
18 State law or common law to the contrary.

19 “(ii) EXCEPTION.—Clause (i) shall
20 not apply with respect to damages in the
21 case of a cause of action for wrongful
22 death if the applicable State law provides
23 (or has been construed to provide) for
24 damages in such a cause of action which
25 are only punitive or exemplary in nature.

1 “(C) PERSONAL INJURY DEFINED.—For
 2 purposes of this subsection, the term ‘personal
 3 injury’ means a physical injury and includes an
 4 injury arising out of the treatment (or failure
 5 to treat) a mental illness or disease.

6 “(2) EXCEPTION FOR GROUP HEALTH PLANS,
 7 EMPLOYERS, AND OTHER PLAN SPONSORS.—

8 “(A) IN GENERAL.—Subject to subpara-
 9 graph (B), paragraph (1) does not authorize—

10 “(i) any cause of action against a
 11 group health plan or an employer or other
 12 plan sponsor maintaining the plan (or
 13 against an employee of such a plan, em-
 14 ployer, or sponsor acting within the scope
 15 of employment), or

16 “(ii) a right of recovery, indemnity, or
 17 contribution by a person against a group
 18 health plan or an employer or other plan
 19 sponsor (or such an employee) for damages
 20 assessed against the person pursuant to a
 21 cause of action under paragraph (1).

22 “(B) SPECIAL RULE.—Subparagraph (A)
 23 shall not preclude any cause of action described
 24 in paragraph (1) against group health plan or
 25 an employer or other plan sponsor (or against

1 an employee of such a plan, employer, or spon-
2 sor acting within the scope of employment) if—

3 “(i) such action is based on the exer-
4 cise by the plan, employer, or sponsor (or
5 employee) of discretionary authority to
6 make a decision on a claim for benefits
7 covered under the plan or health insurance
8 coverage in the case at issue; and

9 “(ii) the exercise by the plan, em-
10 ployer, or sponsor (or employee) of such
11 authority resulted in personal injury or
12 wrongful death.

13 “(C) EXCEPTION.—The exercise of discre-
14 tionary authority described in subparagraph
15 (B)(i) shall not be construed to include—

16 “(i) the decision to include or exclude
17 from the plan any specific benefit;

18 “(ii) any decision to provide extra-con-
19 tractual benefits; or

20 “(iii) any decision not to consider the
21 provision of a benefit while internal or ex-
22 ternal review is being conducted.

23 “(3) FUTILITY OF EXHAUSTION.—An individual
24 bringing an action under this subsection is required
25 to exhaust administrative processes under sections

1 102 and 103 of the Patients’ Bill of Rights Act, un-
 2 less the injury to or death of such individual has oc-
 3 curred before the completion of such processes.

4 “(4) CONSTRUCTION.—Nothing in this sub-
 5 section shall be construed as—

6 “(A) permitting a cause of action under
 7 State law for the failure to provide an item or
 8 service which is specifically excluded under the
 9 group health plan involved;

10 “(B) as preempting a State law which re-
 11 quires an affidavit or certificate of merit in a
 12 civil action; or

13 “(C) permitting a cause of action or rem-
 14 edy under State law in connection with the pro-
 15 vision or arrangement of excepted benefits (as
 16 defined in section 733(c)), other than those de-
 17 scribed in section 733(c)(2)(A).

18 “(g) RULES OF CONSTRUCTION RELATING TO
 19 HEALTH CARE.—Nothing in this title shall be construed
 20 as—

21 “(1) permitting the application of State laws
 22 that are otherwise superseded by this title and that
 23 mandate the provision of specific benefits by a group
 24 health plan (as defined in section 733(a)) or a mul-

1 tiple employer welfare arrangement (as defined in
2 section 3(40)), or

3 “(2) affecting any State law which regulates the
4 practice of medicine or provision of medical care, or
5 affecting any action based upon such a State law.”.

6 (b) EFFECTIVE DATE.—The amendment made by
7 subsection (a) shall apply to acts and omissions occurring
8 on or after the date of enactment of this Act, from which
9 a cause of action arises.

10 **SEC. 303. LIMITATIONS ON ACTIONS.**

11 Section 502 of the Employee Retirement Income Se-
12 curity Act of 1974 (29 U.S.C. 1132) is amended further
13 by adding at the end the following new subsection:

14 “(n)(1) Except as provided in this subsection, no ac-
15 tion may be brought under subsection (a)(1)(B), (a)(2),
16 or (a)(3) by a participant or beneficiary seeking relief
17 based on the application of any provision in section 101,
18 subtitle B, or subtitle D of title I of the Patients’ Bill
19 of Rights Act (as incorporated under section 714).

20 “(2) An action may be brought under subsection
21 (a)(1)(B), (a)(2), or (a)(3) by a participant or beneficiary
22 seeking relief based on the application of section 101, 113,
23 114, 115, 116, 117, 119, or 118(3) of the Patients’ Bill
24 of Rights Act (as incorporated under section 714) to the

1 individual circumstances of that participant or beneficiary,
 2 except that—

3 “(A) such an action may not be brought or
 4 maintained as a class action; and

5 “(B) in such an action, relief may only provide
 6 for the provision of (or payment of) benefits, items,
 7 or services denied to the individual participant or
 8 beneficiary involved (and for attorney’s fees and the
 9 costs of the action, at the discretion of the court)
 10 and shall not provide for any other relief to the par-
 11 ticipant or beneficiary or for any relief to any other
 12 person.

13 “(3) Nothing in this subsection shall be construed as
 14 affecting any action brought by the Secretary.”.

15 **TITLE IV—APPLICATION TO**
 16 **GROUP HEALTH PLANS**
 17 **UNDER THE INTERNAL REV-**
 18 **ENUE CODE OF 1986**

19 **SEC. 401. AMENDMENTS TO THE INTERNAL REVENUE CODE**
 20 **OF 1986.**

21 Subchapter B of chapter 100 of the Internal Revenue
 22 Code of 1986 is amended—

23 (1) in the table of sections, by inserting after
 24 the item relating to section 9812 the following new
 25 item:

“Sec. 9813. Standard relating to patient freedom of choice.”;

1 and

2 (2) by inserting after section 9812 the fol-
3 lowing:

4 **“SEC. 9813. STANDARD RELATING TO PATIENTS’ BILL OF**
5 **RIGHTS.**

6 “A group health plan shall comply with the require-
7 ments of title I of the Patients’ Bill of Rights Act (as
8 in effect as of the date of the enactment of such Act),
9 and such requirements shall be deemed to be incorporated
10 into this section.”.

11 **TITLE V—EFFECTIVE DATES; CO-**
12 **ORDINATION IN IMPLEMEN-**
13 **TATION**

14 **SEC. 501. EFFECTIVE DATES.**

15 (a) GROUP HEALTH COVERAGE.—

16 (1) IN GENERAL.—Subject to paragraph (2),
17 the amendments made by sections 201(a), 301, 303,
18 and 401 (and title I insofar as it relates to such sec-
19 tions) shall apply with respect to group health plans,
20 and health insurance coverage offered in connection
21 with group health plans, for plan years beginning on
22 or after January 1, 2002 (in this section referred to
23 as the “general effective date”) and also shall apply
24 to portions of plan years occurring on and after such
25 date.

1 (2) TREATMENT OF COLLECTIVE BARGAINING
 2 AGREEMENTS.—In the case of a group health plan
 3 maintained pursuant to one or more collective bar-
 4 gaining agreements between employee representa-
 5 tives and one or more employers ratified before the
 6 date of the enactment of this Act, the amendments
 7 made by sections 201(a), 301, 303, and 401 (and
 8 title I insofar as it relates to such sections) shall not
 9 apply to plan years beginning before the later of—

10 (A) the date on which the last collective
 11 bargaining agreements relating to the plan ter-
 12 minates (determined without regard to any ex-
 13 tension thereof agreed to after the date of the
 14 enactment of this Act); or

15 (B) the general effective date.

16 For purposes of subparagraph (A), any plan amend-
 17 ment made pursuant to a collective bargaining
 18 agreement relating to the plan which amends the
 19 plan solely to conform to any requirement added by
 20 this Act shall not be treated as a termination of
 21 such collective bargaining agreement.

22 (b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—
 23 The amendments made by section 202 shall apply with
 24 respect to individual health insurance coverage offered,

1 sold, issued, renewed, in effect, or operated in the indi-
 2 vidual market on or after the general effective date.

3 **SEC. 502. COORDINATION IN IMPLEMENTATION.**

4 The Secretary of Labor, the Secretary of Health and
 5 Human Services, and the Secretary of the Treasury shall
 6 ensure, through the execution of an interagency memo-
 7 randum of understanding among such Secretaries, that—

8 (1) regulations, rulings, and interpretations
 9 issued by such Secretaries relating to the same mat-
 10 ter over which such Secretaries have responsibility
 11 under the provisions of this Act (and the amend-
 12 ments made thereby) are administered so as to have
 13 the same effect at all times; and

14 (2) coordination of policies relating to enforcing
 15 the same requirements through such Secretaries in
 16 order to have a coordinated enforcement strategy
 17 that avoids duplication of enforcement efforts and
 18 assigns priorities in enforcement.

19 **TITLE VI—MISCELLANEOUS**
 20 **PROVISIONS**

21 **SEC. 601. HEALTH CARE PAPERWORK SIMPLIFICATION.**

22 (a) ESTABLISHMENT OF PANEL.—

23 (1) ESTABLISHMENT.—There is established a
 24 panel to be known as the Health Care Panel to De-

1 vise a Uniform Explanation of Benefits (in this sec-
 2 tion referred to as the “Panel”).

3 (2) DUTIES OF PANEL.—

4 (A) IN GENERAL.—The Panel shall devise
 5 a single form for use by third-party health care
 6 payers for the remittance of claims to providers.

7 (B) DEFINITION.—For purposes of this
 8 section, the term “third-party health care
 9 payer” means any entity that contractually
 10 pays health care bills for an individual.

11 (3) MEMBERSHIP.—

12 (A) SIZE AND COMPOSITION.—The Sec-
 13 retary of Health and Human Services shall de-
 14 termine the number of members and the com-
 15 position of the Panel. Such Panel shall include
 16 equal numbers of representatives of private in-
 17 surance organizations, consumer groups, State
 18 insurance commissioners, State medical soci-
 19 eties, State hospital associations, and State
 20 medical specialty societies.

21 (B) TERMS OF APPOINTMENT.—The mem-
 22 bers of the Panel shall serve for the life of the
 23 Panel.

24 (C) VACANCIES.—A vacancy in the Panel
 25 shall not affect the power of the remaining

1 members to execute the duties of the Panel, but
2 any such vacancy shall be filled in the same
3 manner in which the original appointment was
4 made.

5 (4) PROCEDURES.—

6 (A) MEETINGS.—The Panel shall meet at
7 the call of a majority of its members.

8 (B) FIRST MEETING.—The Panel shall
9 convene not later than 60 days after the date
10 of the enactment of the Patients' Bill of Rights
11 Act.

12 (C) QUORUM.—A quorum shall consist of
13 a majority of the members of the Panel.

14 (D) HEARINGS.—For the purpose of car-
15 rying out its duties, the Panel may hold such
16 hearings and undertake such other activities as
17 the Panel determines to be necessary to carry
18 out its duties.

19 (5) ADMINISTRATION.—

20 (A) COMPENSATION.—Except as provided
21 in subparagraph (B), members of the Panel
22 shall receive no additional pay, allowances, or
23 benefits by reason of their service on the Panel.

24 (B) TRAVEL EXPENSES AND PER DIEM.—
25 Each member of the Panel who is not an officer

1 or employee of the Federal Government shall
2 receive travel expenses and per diem in lieu of
3 subsistence in accordance with sections 5702
4 and 5703 of title 5, United States Code.

5 (C) CONTRACT AUTHORITY.—The Panel
6 may contract with and compensate Government
7 and private agencies or persons for items and
8 services, without regard to section 3709 of the
9 Revised Statutes (41 U.S.C. 5).

10 (D) USE OF MAILS.—The Panel may use
11 the United States mails in the same manner
12 and under the same conditions as Federal agen-
13 cies and shall, for purposes of the frank, be
14 considered a commission of Congress as de-
15 scribed in section 3215 of title 39, United
16 States Code.

17 (E) ADMINISTRATIVE SUPPORT SERV-
18 ICES.—Upon the request of the Panel, the Sec-
19 retary of Health and Human Services shall pro-
20 vide to the Panel on a reimbursable basis such
21 administrative support services as the Panel
22 may request.

23 (6) SUBMISSION OF FORM.—Not later than 2
24 years after the first meeting, the Panel shall submit

1 a form to the Secretary of Health and Human Serv-
 2 ices for use by third-party health care payers.

3 (7) TERMINATION.—The Panel shall terminate
 4 on the day after submitting the form under para-
 5 graph (6).

6 (b) REQUIREMENT FOR USE OF FORM BY THIRD-
 7 PARTY CARE PAYERS.—A third-party health care payer
 8 shall be required to use the form devised under subsection
 9 (a) for plan years beginning on or after 5 years following
 10 the date of the enactment of this Act.

11 **SEC. 602. NO IMPACT ON SOCIAL SECURITY TRUST FUND.**

12 (a) IN GENERAL.—Nothing in this Act (or an amend-
 13 ment made by this Act) shall be construed to alter or
 14 amend the Social Security Act (or any regulation promul-
 15 gated under that Act).

16 (b) TRANSFERS.—

17 (1) ESTIMATE OF SECRETARY.—The Secretary
 18 of the Treasury shall annually estimate the impact
 19 that the enactment of this Act has on the income
 20 and balances of the trust funds established under
 21 section 201 of the Social Security Act (42 U.S.C.
 22 401).

23 (2) TRANSFER OF FUNDS.—If, under para-
 24 graph (1), the Secretary of the Treasury estimates
 25 that the enactment of this Act has a negative impact

1 on the income and balances of the trust funds estab-
2 lished under section 201 of the Social Security Act
3 (42 U.S.C. 401), the Secretary shall transfer, not
4 less frequently than quarterly, from the general reve-
5 nues of the Federal Government an amount suffi-
6 cient so as to ensure that the income and balances
7 of such trust funds are not reduced as a result of
8 the enactment of such Act.

○